

65331-4

8/21/2013

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

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

NOTIFICATION

AUG 21 2013

Karen Mardis
Senior Manager
Registration Affairs N.A.
Merial Limited
3239 Satellite Blvd.
Duluth, GA 30096

Subject: Product Names: Frontline Plus for Cats and Frontline Plus for Dogs
EPA Reg. Nos. 65331-4 and 65331-5
Submission date: 7/24/2013
Notifications of collateral labeling and promotional marketing language
OPP Decision Numbers: 481959 and 481960

Dear Ms. Mardis:

The Agency is in receipt of your Applications for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated July 24, 2013 for the products EPA Reg. No. 65331-4 and 65331-5, Frontline Plus for Cats and Frontline Plus for Dogs, respectively. The Registration Division (RD) has conducted a review of these requests for their applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The labels submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at 703-305-6701 or Kaitlin Keller at 703-305-6701.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Gebken".

Richard Gebken
Product Manager 13
Insecticide Branch
Registration Division (7504P)

NOTIFICATION
AUG 21 2013

FRONTLINE®
Plus FOR CATS

Kills fleas, flea eggs & larvae, ticks, & chewing lice

- Fast-acting
- Long-lasting
- Waterproof

Kills ticks, including those that may transmit Lyme disease

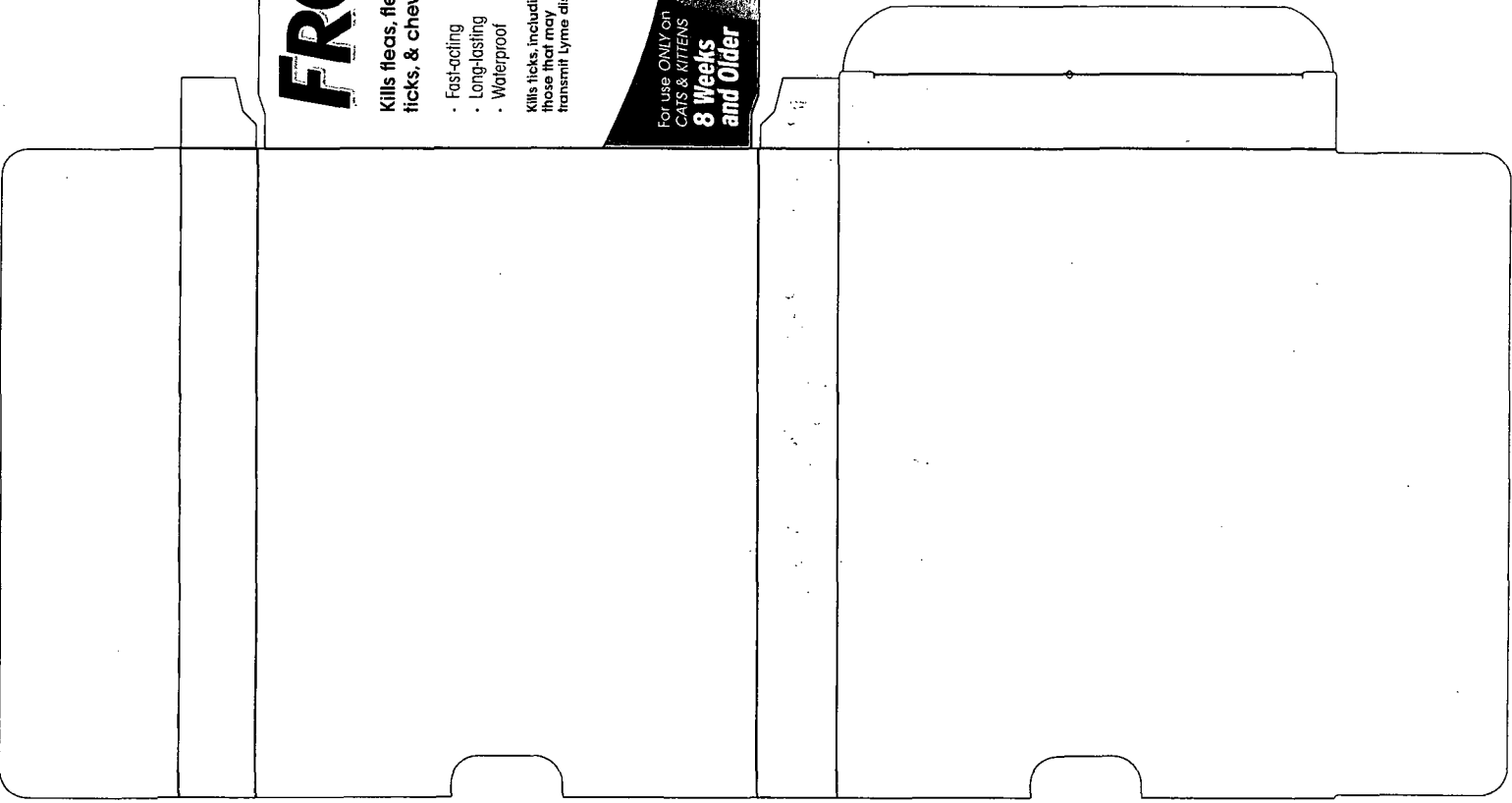
For use ONLY on CATS & KITTENS
8 Weeks and Older

SEE INSIDE FOR USE AND PRECAUTIONS. KEEP OUT OF REACH OF CHILDREN.

CAUTION

Look inside for more details, plus a free pet healthcare guide!

Proven protection against fleas and ticks
also comes with the **SATISFACTION PLUS GUARANTEE™** offered exclusively when you purchase from your veterinarian.



Exclusive Offers!

Only from your Veterinarian

- ♥ SATISFACTION PLUS GUARANTEE™
- ▲ Free FRONTLINE® Plus Offer



FRONTLINE® Plus FOR CATS

For use ONLY on CATS & KITTENS
8 Weeks and Older

3 DOSES

FREE 5x7 Photo Book



\$11.99 Value!

from **snapfish** by hp

Plus Special Savings on Your Next Purchase! BUY 6 DOSES - GET 2 DOSES FREE!

See brochure for details and coupon.

Value-Packed Offers Inside!

For cat use only

FRONTLINE® Plus FOR CATS
8 Weeks and Older

3 DOSES

For use ONLY on CATS & KITTENS

3239 Saddle Bay, Durham, GA 30096-4210, USA
MADE IN FRANCE

FRONTLINE® Plus is a registered trademark of Fort Dodge Animal Health, a division of Wyeth.



FRONTLINE® Plus FOR CATS

It is a solution of fipronil low base in a moist carrier with its loading, de-odorizing and chewing lice for use ONLY on cats and kittens 8 weeks or older.

Directions for Use

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

To kill fleas, flea eggs & larvae, ticks, and chewing lice apply FRONTLINE Plus for Cats as follows:

- **REMOVE APPLICATOR:** Lift and remove the plastic top to expose (oil backing); then peel away the foil. Or use scissors to open.
- **APPLY FRONTLINE Plus:** Part the cat's hair above the shoulder blades, at the base of the neck. Place the applicator 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 Plus FOR CATS:** Do not apply on top of the hair coat. Avoid contact with treated area until dry.

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

Frequency of Application

When used monthly, FRONTLINE Plus completely breaks the life cycle and controls tick and chewing lice infestations. Do not reapply FRONTLINE Plus for 30 days.

FRONTLINE Plus kills adult fleas, flea eggs, and flea larvae for up to six weeks. FRONTLINE Plus also prevents development of all flea stages for up to six weeks. FRONTLINE Plus controls fleas for up to six weeks. However, there is a high risk of reinfestation if the cat has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

FRONTLINE Plus kills ticks for at least one month. A once monthly application is recommended where tick control is needed. FRONTLINE Plus kills all life stages of ticks (larva, nymph and adult). FRONTLINE Plus kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, babesiosis, and anaplasmosis. Frontline Plus kills chewing lice for at least one month. A once monthly application is recommended where chewing lice control is needed.

Satisfaction Plus Guarantee

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

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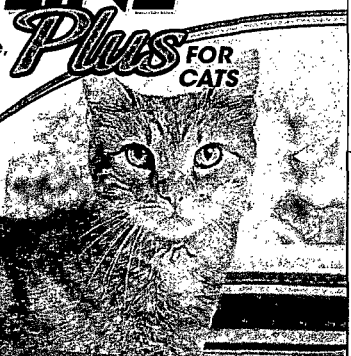
NOTIFICATION

AUG 21 2013

FRONTLINE[®]

6  doses

Kills fleas, flea eggs & larvae,
ticks, & chewing lice



- Fast-acting
- Long-lasting
- Waterproof

Kills ticks, including those that may transmit Lyme disease

For use **ONLY** on
CATS & KITTENS
**8 Weeks
and Older**

SEE PRODUCT INFORMATION FOR FULL DIRECTIONS AND PRECAUTIONARY STATEMENTS
KEEP OUT OF REACH OF CHILDREN
CAUTION



**Proven protection
against fleas and ticks**
also comes with the
SATISFACTION PLUS GUARANTEE™
offered exclusively when you purchase from
your veterinarian.
Look inside for more details, plus a free pet healthcare guide!

Exclusive Offers!

Only from your Veterinarian

♥ SATISFACTION PLUS GUARANTEE™

▲ Free FRONTLINE® Plus Offer

snapfish  by hp

Free!



FRONTLINE® Plus FOR CATS

For use ONLY on CATS & KITTENS

8 Weeks and Older

6 doses

FREE 5x7 Photo Book

\$11.99 Value!



from snapfish  by hp

Plus Special Savings on Your Next Purchase! BUY 6 DOSES - GET 2 DOSES FREE!

See brochure for details and coupon.

Value-Packed Offers Inside!

For cat use only

FRONTLINE® Plus FOR CATS
8 Weeks and Older

Medical Lenders
3239 Shields Blvd
Dublin, CA 94568-4740, USA
MADP, INC. FORTNE
a division of
Frontline Plus
©2013 Medvet Limited, Dublin, CA.
All rights reserved.
1-800-352-9000



FRONTLINE Plus FOR CATS is approved for use on all cats, including breeding, pregnant, and lactating queens.
Apply FRONTLINE Plus to the top of the cat's head, between the ears and the base of the neck. Place the applicator tip just above the ear and squeeze. Apply white contents of the applicator in a single spot.
• APPLY FRONTLINE Plus. For the cat's head, place the applicator tip at the base of the neck. Place the applicator tip just above the ear and squeeze. Apply white contents of the applicator in a single spot.
• APPLY FRONTLINE Plus. For the cat's head, place the applicator tip at the base of the neck. Place the applicator tip just above the ear and squeeze. Apply white contents of the applicator in a single spot.
• APPLY FRONTLINE Plus. For the cat's head, place the applicator tip at the base of the neck. Place the applicator tip just above the ear and squeeze. Apply white contents of the applicator in a single spot.



FRONTLINE Plus FOR CATS provides fast-acting, long-lasting, waterproof treatment and control of fleas, ticks, and chewing lice 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 MAMMALS. DO NOT USE ON OTHER ANIMALS.

To kill fleas, ticks, and chewing lice, and prevent flea infestation, apply FRONTLINE Plus FOR CATS as follows:
• To REMOVE applicator: Lift and remove the plastic tab to expose lot backing; then peel away the foil. Or use scissors to open.
• To APPLY FRONTLINE Plus: Hold upright with foil side toward you and snap applicator top.
• APPLY FRONTLINE Plus. For the cat's head, place the applicator tip at the base of the neck. Place the applicator tip just above the ear and squeeze. Apply white contents of the applicator in a single spot.
• APPLY FRONTLINE Plus. For the cat's head, place the applicator tip at the base of the neck. Place the applicator tip just above the ear and squeeze. Apply white contents of the applicator in a single spot.

Frequency of Application
FRONTLINE Plus remains effective when after bathing, water immersion, or exposure to sunlight, and treats as young as 8 weeks.

FRONTLINE Plus FOR CATS is approved for use on all cats, including breeding, pregnant, and lactating queens. Apply FRONTLINE Plus to the top of the cat's head, between the ears and the base of the neck. Place the applicator tip just above the ear and squeeze. Apply white contents of the applicator in a single spot.

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FRONTLINE Plus kills ticks for at least one month. A once monthly application is recommended where tick control is needed. FRONTLINE Plus kills all stages of ticks (larvae, nymphs and adults). FRONTLINE Plus kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, babesiosis, and anaplasmosis. Application may be needed.

FRONTLINE Plus kills fleas for at least one month. A once monthly application is recommended where flea control is needed. FRONTLINE Plus kills all stages of fleas (eggs, nymphs and adults). FRONTLINE Plus kills fleas that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, babesiosis, and anaplasmosis. Application may be needed.

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 Plus kills chewing lice for up to six weeks. However, FRONTLINE Plus also prevents development of all life stages for up to six weeks. FRONTLINE Plus can control 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.

When used monthly, FRONTLINE Plus completely breaks the flea life cycle and controls tick and chewing lice infestations. Do not reapply FRONTLINE Plus for 30 days.

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SHUT OUT FLEAS, NOT THE CAT.

Prevent a flea infestation before it
begins with FRONTLINE® Plus

FRONTLINE® *Plus*

FRONTLINE® Plus SATISFACTION PLUS GUARANTEE™: Not just a guarantee. Peace of mind.

SATISFACTION
Plus **GUARANTEE™**

The **SATISFACTION PLUS GUARANTEE** is like no other in veterinary medicine:

- Purchase a 3-pack or 6-pack of FRONTLINE Plus from your veterinarian.
- Use the appropriate full product dose of FRONTLINE Plus for at least three consecutive months on every cat and dog in the household.
- If you are not satisfied with FRONTLINE Plus after three months of use, we'll refund your money, provide you with a replacement product, or provide a FREE one-time professional in-home inspection and, if necessary, treatment by Terminix®.

**SATISFACTION PLUS GUARANTEE IS AVAILABLE
EXCLUSIVELY THROUGH VETERINARIANS.**

When you purchase FRONTLINE Plus from your veterinarian, you're not just getting incredible fleekilling power and a top-notch guarantee, you're getting the advice and knowledge of a trusted medical expert – your veterinarian.

Ask your veterinarian for complete details or call 1-877-602-7587.



Proven protection against fleas and ticks.

FRONTLINE Plus helps protect your pet with two tough killing ingredients. One to kill adult fleas and ticks. And another to kill the next generation of flea eggs and larvae.

Fast-acting

- Kills fleas and ticks through contact

Long-lasting

- Kills fleas and ticks for a full month
- Waterproof

Prevents Flea Infestations

- Kills adult fleas, eggs, and larvae

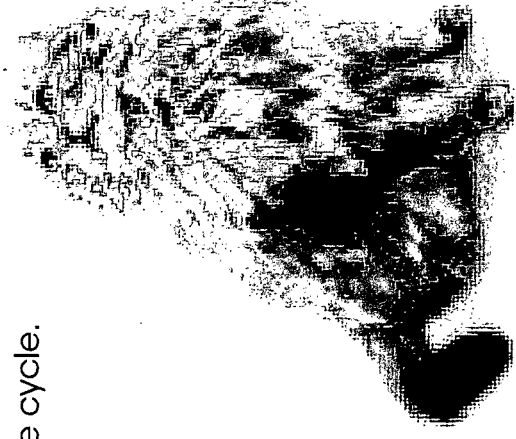
**EXCLUSIVE OFFER
ONLY AVAILABLE AT
YOUR VETERINARIAN!
BUY 6 DOSES OF
FRONTLINE PLUS
AND GET 2 FREE.**

And see the back cover
for a FREE photo book
from Snapfish!



The Facts on Fleas

- Fleas reproduce rapidly – an average adult female can lay more than 40 eggs per day.²
- By the time you see fleas, an infestation may already be established in the environment.
- Flea eggs roll off wherever an infested animal goes, turning your untreated pet into a “salt shaker” that leaves new sources of fleas around the house and yard.
- Carpets, bedding and furniture provide ideal conditions for these immature flea stages to develop into adults.
- The first treatment with FRONTLINE Plus will kill adult fleas, but new fleas will continue to emerge from existing eggs and larvae. It’s important to use FRONTLINE Plus monthly to completely break the flea life cycle.
- Not all flea products are created equal. Use a product like FRONTLINE Plus that provides complete flea control by killing flea eggs, flea larvae, and adult fleas.



BITING ADULTS MAKE UP ONLY A SMALL FRACTION OF A FLEA INFESTATION.

Adult fleas live 100+ days.³

The fleas you see are only 5% of your problem.³

Pupae can survive up to 174 days.³

The larval stage lasts 5 - 11 days.³

Eggs will hatch in 1 - 10 days.³

5% ADULT FLEAS³



35% LARVAE³



10% PUPAE³



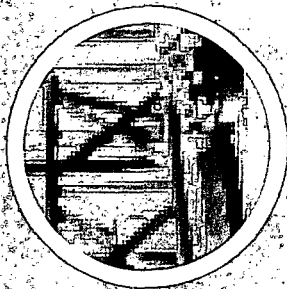
50% EGGS³



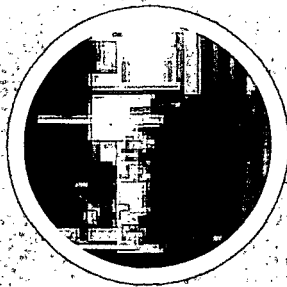
What You Need to Know

The average home provides ideal feeding and breeding grounds for a flea.

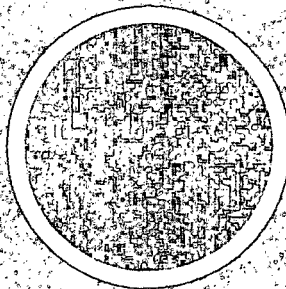
FLEA DEVELOPMENT HOTSPOTS



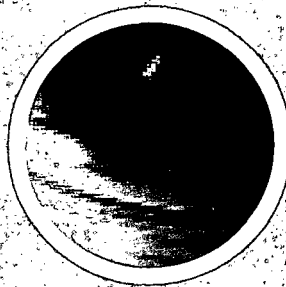
DECKS



UNDER SHRUBS

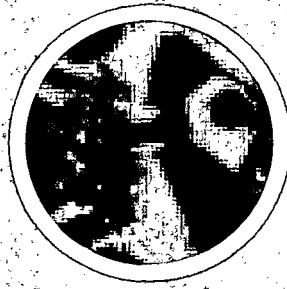


CARPET

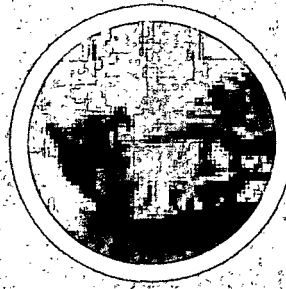


FURNITURE

SOURCES OF FLEAS



URBAN WILDLIFE



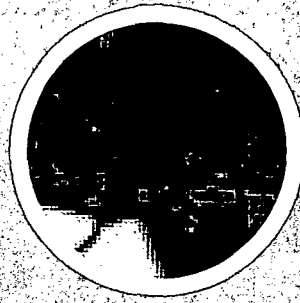
FERAL CATS



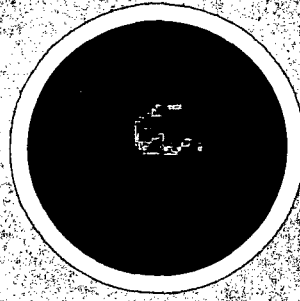
Tick Trouble

- Ticks are more numerous and found in more geographic areas than ever before.⁴ In many places, ticks actively seek hosts year-round.
- Ticks may be brought into your yard by many common carriers, like feral cats, white-tailed deer, raccoons, opossums, wild turkey and coyotes.⁵
- Ticks can spread serious diseases including Lyme disease, Rocky Mountain spotted fever, canine anaplasmosis, ehrlichiosis, babesiosis, and canine hepatozoonosis.
- Some tick species can survive harsh winters. They will even emerge to feed when temperatures are still as cold as 40 degrees F.⁶

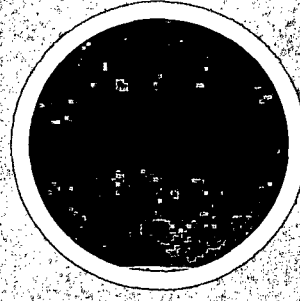
FRONTLINE PLUS KILLS ALL STAGES OF TICKS. SOME OF THE TICKS THAT POSE THE GREATEST THREATS TO PETS IN THE U.S. ARE:



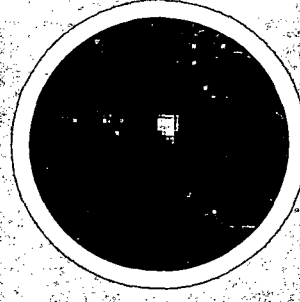
DEER TICK
(*Ixodes scapularis*)



AMERICAN DOG TICK
(*Dermacentor variabilis*)



BROWN DOG TICK
(*Rhipicephalus sanguineus*)



LONE STAR TICK
(*Amblyomma americanum*)

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Frequently Asked Questions

Can I apply FRONTLINE Plus anywhere on my cat's fur?

No. FRONTLINE Plus has to be applied directly to your pet's skin, between the shoulder blades. Be sure to place the applicator tip all the way through the animal's fur to the skin before applying.

Do fleas have to bite my cat to die?

Fleas do not have to bite a treated pet for FRONTLINE Plus to work.

Why am I seeing fleas on my cat after applying FRONTLINE Plus?

Seeing fleas on top of the haircoat after applying FRONTLINE Plus is an indication that FRONTLINE Plus is working. Because FRONTLINE Plus kills fleas by over-stimulating their nervous systems, hyperexcited fleas may move to the top of the haircoat before they die. You may also be seeing new fleas on your pet that just emerged from the environment. FRONTLINE Plus will kill these fleas quickly and, when used monthly, will break the flea life cycle.

² Dryden M. Biology of fleas of dogs and cats. *Comp Cont Ed Pract Vet* 1993;15(4):569-579.

³ Dryden M, Houlton D. Understanding flea biology and control. *Veterinary Practice Staff*. 1990;2(3):6-9.

⁴ Dryden MW. Flea and tick control in the 21st century, challenges and opportunities. *Vet Derm*. 2009;20:435-440.

⁵ Blagburn BL, et al. Biology, treatment and control of flea and tick infestations. *Vet Clin Small Anim*. 2009;39:1173-1200.

⁶ Sonenshine DE. Life Cycles of Ticks, In: Sonenshine DE, ed, *Biology of Ticks*, vol. 1. New York: Oxford University Press; 1991:51-66.

Can my cat be bathed or go swimming after FRONTLINE Plus has been applied?

Yes. FRONTLINE products are waterproof and remain effective after normal swimming and bathing. Your cat should be kept dry for 24 hours after FRONTLINE Plus has been applied.

I applied FRONTLINE Plus two weeks ago - why do I still see fleas?

You are seeing new fleas that hatched from eggs and larvae present before the first treatment of FRONTLINE Plus. Keep treating monthly for at least 3 months to bring the existing flea infestation under control. For effective flea and tick control, apply FRONTLINE Plus monthly throughout the year.

Do I need to use a flea and tick product on my indoor-only cat?

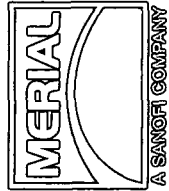
Yes. Although your cat may not go outside, you, or other pets in the household, may bring fleas into the home. These fleas may infest the untreated cat or lead to a flea infestation in the house.

If you have any questions about flea or tick control, please contact your veterinarian or call our technical experts at **1-800-660-1842 (Monday - Friday, 8am - 7pm ET)**.

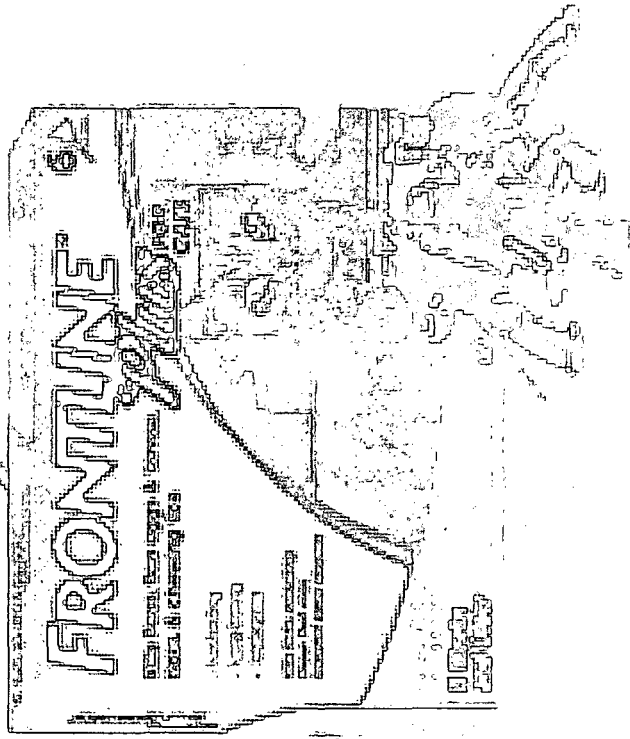
For more information, visit www.FRONTLINE.com.

BUY 6 DOSES*
GET 2 FREE OR
BUY 3 DOSES*
GET ONE FREE

**MANUFACTURER'S COUPON-REDEEMABLE ONLY
 AT YOUR VETERINARY CLINIC. EXPIRES 12/31/14**
 *of the same product in the same size at one time.



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19/21

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PET OWNER, PLEASE PRINT THE FOLLOWING INFORMATION:

Name: _____

Address: _____

City: _____ State: _____ Zip: _____

E-mail: _____

By providing your email address and cell number, you agree to receive special coupons, offers and information from Merial.

Complete the following for your free dose(s) of FRONTLINE Plus: PRODUCT: <input checked="" type="checkbox"/> FRONTLINE Plus	What quantity of FRONTLINE Plus product did you buy?	<input type="checkbox"/> 3 Doses	<input type="checkbox"/> 6 Doses
	<input type="checkbox"/> Dogs up to 22 lbs. <input type="checkbox"/> Dogs 23-44 lbs.	<input type="checkbox"/> Dogs 45-88 lbs. <input type="checkbox"/> Dogs 89-132 lbs.	<input type="checkbox"/> Cats & Kittens

13FLPPB3

13FLPPB6

Redeem this coupon by returning it to:

**FRONTLINE
Program Headquarters
P.O. Box 4060
South Bend, IN 46634**

STAMP CLINIC INFORMATION HERE

[Empty box for stamping clinic information]

FOR VETERINARY CLINIC USE ONLY:

Merial Account #: _____ Rewards Staff ID #: _____

Staff Member Name: _____

Veterinary Hospital: _____

Address: _____

City: _____ State: _____ Zip: _____

Coupon request must be redeemed on or before 12/31/14 and should be postmarked on or before 3/1/15. Offer good only on FRONTLINE Brand Products applied in a veterinary clinic. Merial not responsible for veterinary fees or expenses charged for product application. Merial will only provide credit for this coupon to a Merial veterinary practice account that has purchased FRONTLINE Brand Products from Merial, in accordance with the Sales Policy for companion animal products. Good only in continental United States and Hawaii. Void where prohibited or restricted by law. This form must accompany request; reproductions or other copies will not be accepted. Fraudulent submission could result in Federal prosecution under mail fraud statutes (Title 18, United States Code, Section 1341 and 1342) and applicable state laws. May not be combined with any other offer from FRONTLINE Brand Products.

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20/21

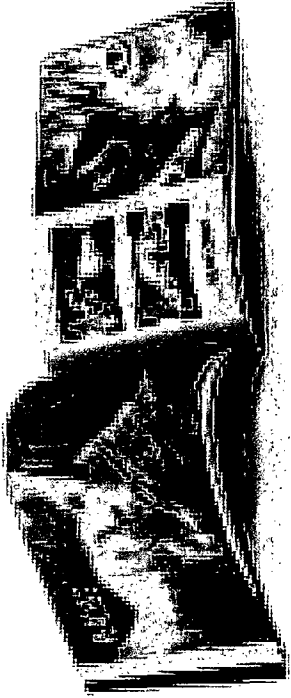


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submission could result in federal prosecution under mail fraud statutes (18 U.S.C. 1341 and 1342) and applicable laws. May not be combined with any other offer from ONLINE Brand Products.

FREE PHOTO BOOK! \$17.99 Value



Create a beautiful 5" x 7" soft cover
photo book that's all yours!

Gift Code XXXXXXXXXXXXXXX



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\$1.99 Shipping & Handling applies.*

Snapfish Terms and Conditions:
Offer is for one free 20-page 5" x 7" Soft Cover Photo Book from Snapfish. Customer pays for additional pages over 20 pages. Limit two photo book credits per account may be used during the promotion period. Enter promo code during the checkout process. Not valid on Disney, Nickelodeon Suites Resorts, Warner Bros., Dr. Seuss, and Sesame Street themed products. Enter Promo code on this insert at www.snapfish.com/frontlinegift to receive offer. Promo codes are valid for single-use only. Offer expires December 31, 2014. Offer applies to mail-order purchases only and cannot be used for in-store pick up. All shipping and tax charges apply. Offer may only be used once and not in conjunction with any other offer. Offer valid for U.S. FRONTLINE Plus customers only. *Subject to change.



®FRONTLINE is a registered trademark of Merial, and
™SATISFACTION PLUS GUARANTEE is a trademark of Merial.
®TERMINIX is a registered trademark of The Terminix International
Company Limited Partnership. ©2013 Merial Limited, Duluth, GA. All
rights reserved. FLE13CNVETPKGBROCHURE (06/13).

FRONTLINE[®] Plus

21/21