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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION 10411

July 28, 2011

Karen C. Cunningham Head, Regulatory Affairs Merial Limited 3239 Satellite Blvd. Building 500, Office 113 Duluth, GA 30096-4640

Subject:

Application for Pesticide Amendment Frontline Plus for Dogs EPA Reg. No. 65331-5 Your Submission Dated May 24, 2011 Decision No: 449978

Dear Ms. Cunningham:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy of the label is enclosed for your records.

If you have any questions contact Driss Benmhend at 703-308-9525 or by e-mail at: Benmhend.driss@epa.gov.

Sincerely.

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

Enclosure: Label stamped "Accepted"



Step 1. **OPEN** Applicator Hold upright with foil side toward you and snap applicator tip.

Step 2.

APPLY FRONTLINE Plus

Part the dog's hair between the shoulder blades. Place the applicator tip just above the skin and squeeze. Apply entire contents of the applicator in a single spot directly onto the dog's skin. Do not apply on top 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



For use ONLY on DOGS & PUPPIES 8 weeks or

ing, long-lasting, waterproof treatment trol of fleas, flea eggs & larvae, ticks,

| ACTIVE INGREDIENTS | |
|---------------------|--|
| fipronil: | |
| (S)-methoprene | |
| INERT INGREDIENTS | |
| TOTAL | |
| KEEP OUT OF REACH O | |

CAUTION

FRONTLINE® Plus for Dogs:

- Fleas
 Kills fleas, flea eggs and flea larvae
 Prevents all flea stages (eggs, larvae, pupae)
 Free desine
- Stops existing infestations and prevents establishment of new infestations
 Kills fleas which may cause flea allergy
- dermatitis Ticks
- Ticks Kills all life stages of ticks (larva, nymph and adult), including brown dog ticks (Rhipicephalus sarguineus), American dog ticks (Dermacentor variabilis), lone star ticks (Ambhyamma americanum) and deer ticks brades creaturdati)
- (kades scapilaris) (kades scapilaris) Kills floks that may transmit Lyme disease, Rocky Mountain Spotted Fever, haemobartoneliosis, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases
- Lice
- Rapidly eliminates chewing lice infestations

- all dogs, including: Breeding, pregnant, and lactating bitches Puppies as young as 8 weeks

Mites Aids in control of sarcoptic mange infestations Mosquitoes Kills mosquitoes FRONTLINE Plus is approved for use on

ACCEPTED JUL 2 8 2011

inder the Federal Insecticide, Fundicide, nd Rodenticide Act, as amended, for the pesticide registered under:

Kills fleas, flea eggs & larvae, ticks & chewing lice & mosquitoes, Fast-acting Long-lasting . FOR DO Waterproof EPA Reg. No. 65331-5 EPA Est. 65331-FR-2 Kills ticks, including those that may MADE IN FRANCE transmit Lyme disease ERT INGREDIENTS: 81.4% DTAL: 100% Intains 1-0.091 ft oz (2.68 mL) applie monthly dose or use ONLY on DOGS 45_{to} 2 88 Ibs 000000 PIPETTE PLACEMENT SIMULATION 037 See inside panels for FIRST AID and PRECAUTIONARY KEEP OUT OF REACH OF CHILDREN

FRONT

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One spot application is all that's needed: FRONTLINE Plus spreads from the single point of application, rapidly covering the entire dog and localizing in the baric, on the surface of the skin and in the sebaceous glands. These glands act as a reservoir, continuously replenishing FRONTLINE Plus and the skin and hair coat, so it keeps working even if the dog gets wet. Fleas, thick and chewing lice are killed quickly after coming into contact with a treated dog. Fleas and ticks do not need to bite the dog in order to die. DIFECTIONS FOR USE

control fleas for up to three months, however, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthy 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, anaplasmosis and other tick-borne diseases. FRONTLINE Plus kills chewing lice for at least one month. A once monthly application is recommended where chewing lice control is needed.

needed. FRONTLINE Plus aids in the control of sarcoptic mange infestations. Multiple monthly treatments are recommended for the elimination of miles. FRONTLINE Plus kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days with a monthly application.

STORAGE AND DISPOSAL

nate water, food, or feed by storage Do not con

STORAGE. Store unused product in original container, 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

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 so by a poison control center or doctor. Do not give anything by

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then continue rinsing eye. Call a poison control center or doctor for treatment advice. **IF ON SKIN OR CLOTHING:** Take off centersident alother units

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

Control center or account of neutrinein duvice. PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS. CAUTION. Hormful 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 thoroco tobacco

HAZARDS TO DOMESTIC ANIMALS.

HAZARDS TO DOMESTIC ANIMALS. For external use only. Do not use on pupples under 8 weeks of age. Individual sensitivities, while area, 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 pet has an unusual reaction to the initial 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, debilitated or aged animals. Call 1-800-660-1842, Monday-Friday, 8am-8pm EST. PHYSICAL OR CHEMICAL HAZARDS

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

HOW SUPPLIED

How Supplied for easy and convenient treatment, FRONTLINE Plus for Dogs is available in sizes for use ONLY on small dogs and pupples 8 weeks or older and up to 22 lbs, medium dogs 23–44 lbs, large dogs 45–88 lbs, and extra large dogs 89–132 lbs.

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 navel. Buyer assumes all risk of Indicated on the acue, buyer assumes all risk of use and handling of this material when such use and handling are contrary to label instructions. Merial Limited 3239 Sciettin Play Duluth, GA 37096-4740, USA

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For use ONLY on DOGS

4 lbs

For use ONLY on DOGS 89_{to}

20 MAY 2011 -TR 'A. Reg. No:_



To kill feas, fea eggs & larva, ficks, chewing lice and mosquitoes apply FRONTLINE Plus for Dogs as follows: • OPEN Applicator Hold upright with foil side toward you and snap applicator fip Hold upright with foil side toward you and snap applicator lip. -APPLY FRONTLINE Plus Part the dog's hair between the shoulder blades. Place the applicator tip just above the skin and squeeze. Apply entire contents of the applicator in a single spot directly onto the animal's skin. Do not apply on top of the hair coat. Avoid contact with treaded area unfil dry. FRONTLINE Plus is approved for use on all dogs, including breeding, pregnant, and lactating bitches and puppies as young as 8 weeks. FRONTLINE Plus remains effective even after bathing, water immersion, or exposure to sunlight. FRESUENCY OF APPLICATION

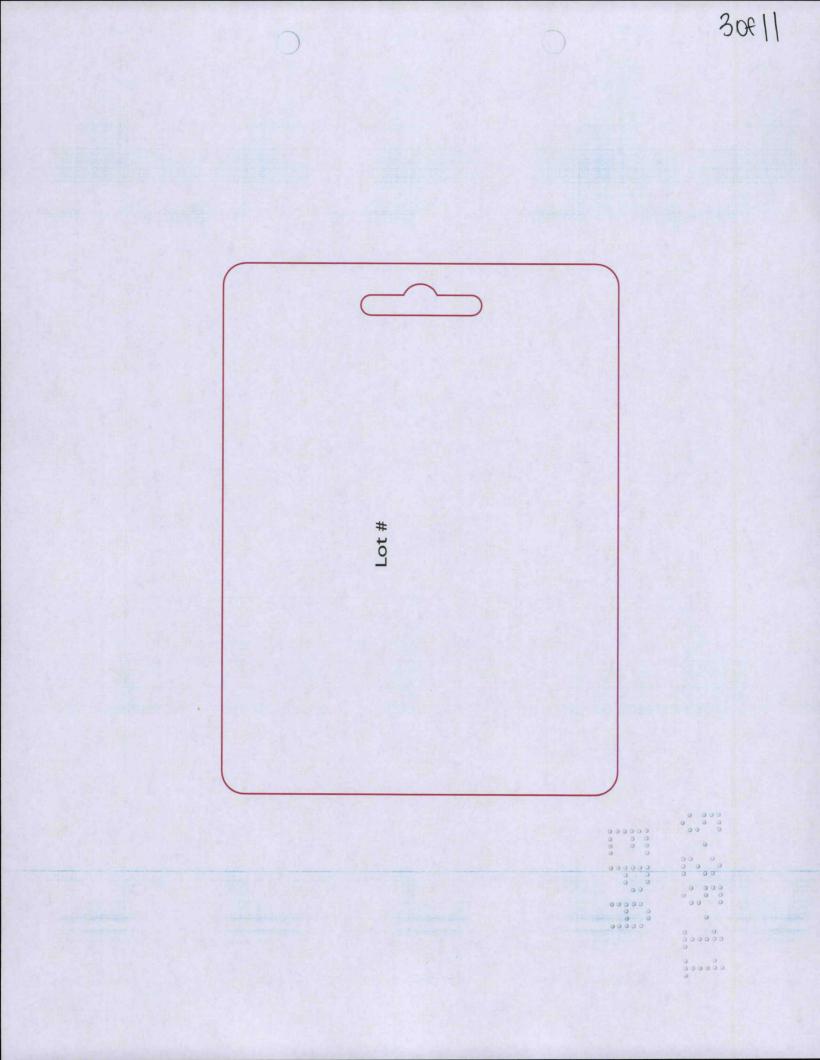
ticks do not need to bite the dog in order to die. DIRECTIONS FOR USE It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. TO PIREVENT HARM TO YOU AND YOUR PET, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON TO kill fleas, flea eggs & larva, ticks, chewing lice

Dathing, water impersion, or exposure to sumigint. **FREQUENCY OF APPLICATION** When used monthly, FRONTLINE Plus completely breaks the flag life cycle and controls tick and chewing lice infestitions. Do not reapply FRONTLINE Plus kills adult flags, flag eggs, and fleg largues the value of the months, FRONTLINE Plus also arevents development of all flags tances

Plus also prevents development of all flea stages for up to three months. FRONTLINE Plus can

Contains 1-0.023 fl oz (0.67 mL) applicator Contains 1-0.045 fl oz (1.34 mL) applicator Contains 1-0.136 fl oz (4.02 mL) applicator

INSIDE | PANELS





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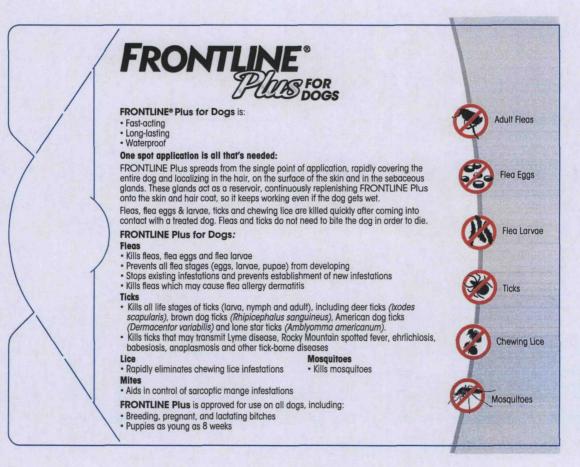
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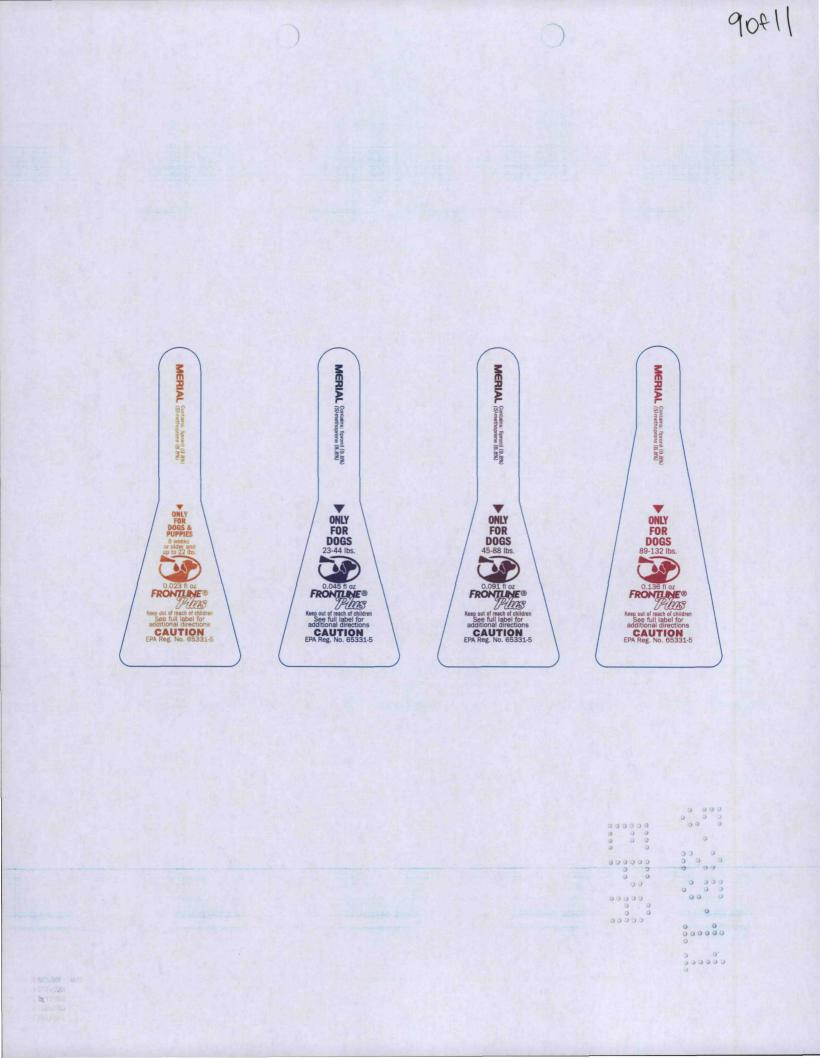


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80411 FRONTLINE FRONTLINE FRONTLINE FRONTLINE FRON LINE 0.045 fl oz Lot # 0.045 fl oz Lot # 0.023 fl oz Lot # 0.023 fl oz Lot # 0.023 fl oz Lot # 0.045 fl oz Lot # DOG 22 DOG 22 DOG 22 DOG 44 DOG 44 DOG 44 RONTLINE FRONTLINE FRONTLINE RONTLINE LINE AITS 0.136 ft oz Lot # DOG 132 pose foil backing: there e foil. Or use scissors (0.091 ft oz Lot # DOG 88 0.091 fl oz Lot # 0.136 fl.oz Lot # 0.091 fl oz Lot # 0.136 fl oz DOG 88 DOG 88 DOG 132 DOG 132 0 000 000 0000 00000 00





For use ONLY on DOGS & PUPPIES 8 weeks or older: Fast-acting, long-lasting, waterproof treatment and control of fleas, flea eggs & larvae, ticks, chewing lice, sarcoptic mites and mosquitoes.

ACTIVE INGREDIENTS

| fipronil: | |
|-------------------|--|
| (S)-methoprene | |
| INERT INGREDIENTS | |
| TOTAL | |

KEEP OUT OF REACH OF CHILDREN CAUTION

FRONTLINE® Plus for Dogs:

Fleas

- Kills fleas, flea eggs and flea larvae
- Prevents all flea stages (eggs, larvae, pupae) from developing Stops existing infestations and prevents establishment of new infestations
- Kills fleas which may cause flea allergy dermatitis
- Ticks
- ICKS
 Kills 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*)
 Kills ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, haemobartonellosis, ehrlichiosis, babesiosis, americaned ether tick there disease.
- anaplasmosis and other tick-borne diseases
- Lice

Rapidly eliminates chewing lice infestations

- Mites Aids in control of sarcoptic mange infestations
- Mosquitoes

- Kills mosquitoes
 FRONTLINE Plus is approved for use on all dogs, including:

Including:
Breeding, pregnant, and lactating bitches
Puppies as young as 8 weeks
One spot application is all that's needed:
FRONTLINE Plus spreads from the single point of application, rapidly covering the entire dog 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 Plus onto the skin and hair coat, so it keeps working even if the dog gets wet.
Fleas, ticks and chewing lice are killed quickly after coming into contact with a treated dog. Fleas and ticks do not need to bite the dog in order to die.

dog in order to die

dog in order to die. **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 DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS. To kill fleas, flea eggs & larva, ticks, chewing lice and mosquitoes apply FRONTLINE Plus for Dogs 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. • APPLY FRONTLINE Plus Part the dog's hair between the shoulder blades. Place the applicator

APPLY FRONTLINE Plus
 Part the dog's hair between the shoulder blades. Place the applicator
 tip just above the skin and squeeze. Apply entire contents of the
 applicator in a single spot directly onto the animal's skin. Do not apply
 on top of the hair coat. Avoid contact with treated area until dry.
 FRONTLINE Plus is approved for use on all dogs, including breeding,
 pregnant, and lactating bitches and puppies as young as 8 weeks.



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

Immersion, or exposure to sunlight. FREQUENCY OF APPLICATION 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. FRONTLINE Plus kills adult fleas, flea eggs, and flea larvae for up to three months, FRONTLINE Plus also prevents development of all flea stages for up to three months. FRONTLINE Plus can control fleas for up to three months, however, if there is a high risk of reinfestion or if the net hos fleas which may cause flea dilerary of reinfestation or if the pet has fleas which may cause flea allergy

of reintestation of if the per has head which may cause head hergy 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 ficks that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, anglasmosis and other tick-borne diseases.

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

FRONTLINE Plus aids in the control of sarcoptic mange infestations. Multiple monthly treatments are recommended for the elimination of mites

FRONTLINE Plus kills mosquitoes within 24 hours for up to 7 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, out of reach of children and animals.

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 lobal with your top selling.

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 so by a poison control center or doctor. Do not give anything by mouth to an

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

Tor 15-20 minutes. Remove contact tenses, it 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 puppies 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. 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, 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. *HOW SUPPLIED*

HOW SUPPLIED

For easy and convenient treatment, FRONTLINE Plus for Dogs is available in sizes for use ONLY on small dogs and puppies 8 weeks or older and up to 22 lbs., medium dogs 23–44 lbs., large dogs 45–88 lbs., and extra large dogs 89–132 lbs.

WARRANTY

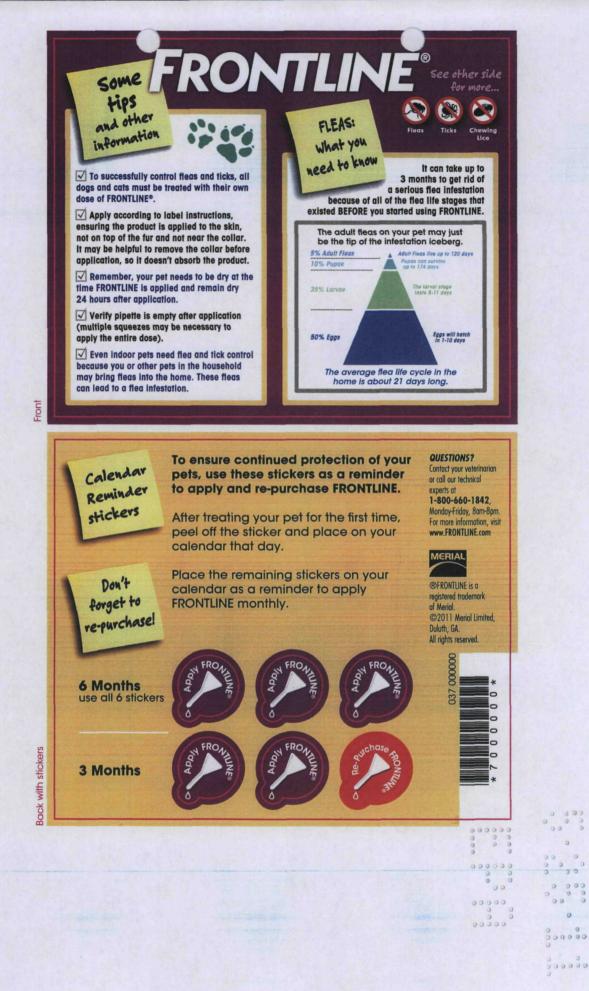
To the extent consistent with applicable raw seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer course all risk of use and handling of this material when such use and handling are contrary to label instructions.

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