

65331-3

03-24-2004

1/13



Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0080, Approval expires 2-28-95

	United States	<input type="checkbox"/> Registration	OPP Identifier Number
	Environmental Protection Agency	<input type="checkbox"/> Amendment	
	Washington, DC 20460	<input checked="" type="checkbox"/> Other	

Application for Pesticide - Section I

1. Company/Product Number 65331-3	2. EPA Product Manager Ms. Linda Arrington	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Frontline Top Spot for Dogs	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Merial Limited 3239 Satellite Blvd. Duluth, GA 30096 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	NOTIFICATION MAR 24 2004
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.	
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.	

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

NOTIFICATION Per PR-Notice 98-10. This notification is consistent with the guidance in PR Notice 98-10 and the requirements of EPA's regulations at 40 CFR 156.10 and 40 CFR 152.46, and no other changes have been made to the labeling or the Confidential Statement of Formula (CSF) 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 guidance of PR-Notice 98-10 and the requirements of 40 CFR 156.10 and 40 CFR 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.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt. 6 oz.	No. per container 3 and 6	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
		If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 0.023, 0.045, 0.091 and 0.136 fl. oz.		5. Location of Label Directions <input checked="" type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other Printed	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Timothy A. Dotson	Title Technical Director	Telephone No. (Include Area Code) 678-636-3713
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		5. Date Application Received (Stamped)
2. Signature 	3. Title Technical Director	
4. Typed Name Timothy A. Dotson	5. Date 3/11/04	

FRONTLINE
Top Spot[®]
for dogs

For Dogs & Puppies 8 weeks or older and up to 22 lbs.
For Dogs 23-44 lbs.
For Dogs 45-88 lbs.
For Dogs 89-132 lbs.

3(6)
Applicators

FRONTLINE

Kills fleas, ticks, chewing lice & mosquitoes

Top Spot
for dogs


- Convenient spot treatment for fast-acting, long-lasting control of fleas, ticks and chewing lice
- Kills mosquitoes
- Waterproof

For Dogs & Puppies 8 weeks or older and up to 22 lbs.
For Dogs 23-44 lbs.
For Dogs 45-88 lbs.
For Dogs 89-132 lbs.

ACTIVE INGREDIENTS	
fipronil	9.7%
INERT INGREDIENTS	90.3%
TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN
CAUTION

Contains 3(6)-0.023 fl oz (0.67 ml) applicators
 Contains 3(6)-0.045 fl oz (1.34 ml) applicators
 Contains 3(6)-0.091 fl oz (2.68 ml) applicators
 Contains 3(6)-0.136 fl oz (4.02 ml) applicators

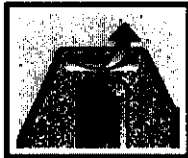


Lift Here To Open

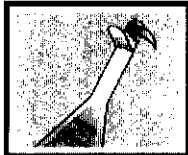
MERIAL

(Prototype Graphics)

How to Apply **FRONTLINE®**
Top Spot®
for dogs



1. To Remove Applicator from Child-Resistant Package
Use scissors. Or lift and remove plastic tab to expose foil, then peel down.



2. To Open Applicator
Hold upright and snap applicator tip away from face and body.



3. To Apply FRONTLINE®
Place applicator tip through animal's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the animal's skin.

INSERT COVER TAB HERE

Questions or Comments?
Call: 1-800-660-1842



FRONTLINE®

Top Spot®

for dogs

For Dogs & Puppies 8 weeks or older and up to 22 lbs.
 For Dogs 23-44 lbs.
 For Dogs 45-88 lbs.
 For Dogs 89-132 lbs.

FRONTLINE provides convenient and effective flea, tick, chewing lice and mosquito control for (dogs and puppies 8 weeks or older and up to 22 lbs., dogs weighing 23-44 lbs., dogs weighing 45-88 lbs., dogs weighing 89-132 lbs.).

- **Fast-acting and long-lasting**
- **Prevents reinfestation**
- **Convenient to use**
- **Kills newly emerged adult fleas before they lay eggs**
- **Controls fleas which may cause flea allergy dermatitis**
- **Kills all stages of brown dog ticks, American dog ticks, lone star ticks and deer ticks (which may carry Lyme disease)**
- **Kills mosquitoes**
- **Rapidly eliminates infestations with chewing lice**
- **Aids in control of sarcoptic mange infestations**
- **Can also be used on breeding, pregnant and lactating bitches**
- **Waterproof**

FRONTLINE contains the active ingredient fipronil that effectively targets fleas, ticks, chewing lice and mosquitoes. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity.



Flea Adult



Brown Dog Tick



Lone Star Tick



Deer Tick



American Dog Tick



Chewing Lice



Mosquito

036 XXXXXX

5113

NOTIFICATION

MAR 24 2004

3(6) Applicators
For Dogs & Puppies 8 weeks or older and up to 22 lbs.
For Dogs 23-44 lbs.
For Dogs 45-88 lbs.
For Dogs 89-132 lbs.

FRONTLINE
Top Spot
for dogs



FRONTLINE[®]

Top Spot[®]

for dogs

FRONTLINE TOP SPOT FOR DOGS provides convenient and effective flea, tick, chewing lice and mosquito control for (dogs and puppies 8 weeks or older and up to 22 lbs., dogs weighing 23-44 lbs., dogs weighing 45-88 lbs., dogs weighing 89-132 lbs.)

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 DOGS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.**

To kill fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease), chewing lice and mosquitoes, apply to dogs and puppies (8 weeks or older) as follows:

Hold applicator upright and snap applicator tip away from face and body. Place applicator tip through animal's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the animal's skin. Avoid superficial application to the animal's hair. Only one applicator per treatment is needed.

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

FRONTLINE TOP SPOT FOR DOGS can also be used for the treatment and control of mosquitoes, and flea, tick and chewing lice infestations on breeding, pregnant and lactating bitches.

Frequency Of Application

When used monthly, FRONTLINE TOP SPOT FOR DOGS completely controls flea, tick and chewing lice infestations. Research demonstrates that FRONTLINE kills adult fleas for up to three months. Although FRONTLINE can control fleas for up to three months, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

FRONTLINE kills ticks for at least one month. A once monthly application is recommended where tick control is needed.

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

With a monthly application, FRONTLINE kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Merial Limited
3239 Satellite Blvd.
Duluth, GA 30096-4640, USA

MADE IN FRANCE

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EPA Reg. No. 65331-3
EPA Est. 65331-FR-2
(EPA Est. 65331-DEU-1)
(EPA Est. 65331-GA-1)
(EPA Est. 74528-CHE-1)



Please call our experts at 1-800-660-1842 if you have any questions or comments about flea, tick, lice and mosquito control or FRONTLINE TOP SPOT.



FRONTLINE[®]
Top Spot[®]
for dogs

For Dogs & Puppies 8 weeks or older and up to 22 lbs.
For Dogs 23-44 lbs.
For Dogs 45-88 lbs.
For Dogs 89-132 lbs.



LOT NO :

For animal use only

FRONT

BACK

6/13

FRONTLINE® Top Spot® for dogs

FOR DOGS & PUPPIES 8 weeks or older
**Convenient spot treatment for fast-acting,
long-lasting control of fleas, ticks and chewing lice.**
FRONTLINE® also kills mosquitoes.

ACTIVE INGREDIENT

fipronil	9.7%
INERT INGREDIENTS	90.3%
TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FRONTLINE® provides convenient and effective flea, tick, chewing lice and mosquito control for dogs and puppies.

- Fast-acting and long-lasting
- Prevents reinfestation
- Convenient to use
- Kills newly emerged adult fleas before they lay eggs
- Controls fleas which may cause flea allergy dermatitis
- Kills all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease)
- Kills mosquitoes
- Rapidly eliminates infestations with chewing lice
- Aids in control of sarcoptic mange infestations
- Can also be used on breeding, pregnant and lactating bitches
- Waterproof

FRONTLINE® contains the active ingredient fipronil that effectively targets fleas, ticks, chewing lice and mosquitoes. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity.

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, all stages of **brown dog ticks, American dog ticks, lone star ticks, and deer ticks** (which may carry Lyme disease), chewing lice and mosquitoes, apply to dogs or puppies (8 weeks or older) as follows:

Remove applicator from child-resistant package. Hold applicator upright and snap applicator tip away from face and body. Place applicator tip through animal's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the animal's skin. Avoid superficial application to the animal's hair. Only one applicator per treatment is needed.

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

FRONTLINE® TOP SPOT FOR DOGS can also be used for the treatment and control of mosquitoes, and flea, tick and chewing lice infestations on breeding, pregnant and lactating bitches.



037 XXXXX

FREQUENCY OF APPLICATION

When used monthly, FRONTLINE® TOP SPOT FOR DOGS completely controls flea, tick and chewing lice infestations. Research demonstrates that FRONTLINE® kills adult fleas for up to three months. Although FRONTLINE® can control fleas for up to three months, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed. FRONTLINE® kills ticks for at least one month. A once monthly application is recommended where tick control is needed. FRONTLINE® kills chewing lice for at least one month. A once monthly application is recommended where chewing lice control is needed. With a monthly application, FRONTLINE® kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days. FRONTLINE® remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply FRONTLINE® for 30 days.

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: Do not reuse 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.

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: Wash with plenty of soap and water. Get medical attention if irritation persists.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

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 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

FLAMMABLE: Keep away from heat and open flame.

HOW SUPPLIED

For easy and convenient treatment, FRONTLINE® TOP SPOT FOR DOGS is available in sizes for 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

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. 65331-3

Merial Limited
3239 Satellite Blvd.
Duluth, GA 30096-4640, USA

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DOGS compliance card x3 - Front

FRONTLINE

"Flea, Tick, Chewing Lice and Mosquito Protection Card" **Top Spot**
for dogs

Apply FRONTLINE® monthly, or as needed,
for continuous protection against fleas, ticks and chewing lice.

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Pet's Name:

Date of first treatment:



Month 1 Month 2 Month 3

Place stickers on calendar as a reminder to apply FRONTLINE®.

037 XXXXXX

(Prototype Graphics)

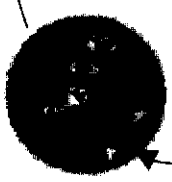
DOGS compliance card x3 - Back

Remove the adhesive backing and attach to your refrigerator door.

Fleas, Ticks, Chewing Lice and Mosquitoes can be a year-round problem!

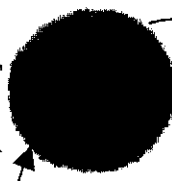
Spring

Prevention
Fleas and ticks start to breed more quickly as spring progresses.



Summer

Prevention - Treatment
The period of highest risk. Summer temperatures and humidity can quickly lead to huge infestations.



Winter

Prevention
The risk is still there. With the cold weather, fleas can breed in your warm home.



Autumn

Prevention - Treatment
Prevents reinfestation from newly emerged adult fleas and all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease).



How To Use Chewing Lice and Mosquito Protection Card

The colored circles on the front of this card will help you determine the appropriate **REAPPLICATION**:

1. Write the date of your pet's first treatment in the box above.
2. After washing your pet, peel off the sticker corresponding to the treatment month.
3. Place the sticker on the pet's collar, neck or back. Do not use on dogs with sensitive skin or on puppies less than 12 weeks of age.



(Prototype Graphics)

DOGS compliance card x6 - Front

FRONTLINE

"Flea, Tick, Chewing Lice and Mosquito Protection Card" **Top Spot** for dogs

Apply FRONTLINE® monthly, or as needed, for continuous protection against fleas, ticks and chewing lice.

Pet's Name:

Date of first treatment:



Month 1	Month 2	Month 3
Month 4	Month 5	Month 6

Place stickers on calendar as a reminder to apply FRONTLINE®.

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D37 XXXXXX

(Prototype Graphics)

9/13

DOGS compliance card x6 - Back

Remove the adhesive backing and attach to your refrigerator door.

Fleas, Ticks, Chewing Lice and Mosquitoes can be a year-round problem!

Spring

Prevention

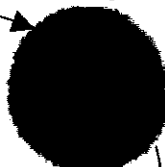
Fleas and ticks start to breed more quickly as spring progresses.



Summer

Prevention - Treatment

The period of highest risk. Summer temperatures and humidity can quickly lead to huge infestations.



Winter

Prevention

The risk is still there. With the cold weather, fleas can breed in your warm home.

Autumn

Prevention - Treatment

Prevents reinfestation from newly emerged adult fleas and all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease).

Flea, Tick, Chewing Lice and Mosquito Protection Card

Instructions for Use

The calendar stickers on the front of this card will help you remember to apply FRONTLINE®.

1. Write the date of your pet's first treatment in the box shown.
2. After treating your pet, peel off the sticker corresponding to the current month.
3. Place the remaining stickers on your calendar as a reminder to apply FRONTLINE® monthly or as needed.



(Prototype Graphics)

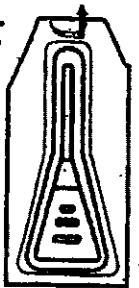
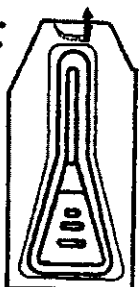
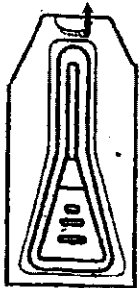
10/13

FRONTLINE®
Top Spot®

FRONTLINE®
Top Spot®

FRONTLINE®
Top Spot®

FRONTLINE®
Top Spot®



TO REMOVE APPLICATOR:
Use scissors. Or lift and remove
plastic tab to expose foil,
then peel down.

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then peel down.

TO REMOVE APPLICATOR:
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Dog 22
0.023 fl oz
Lot #

Dog 22
0.023 fl oz
Lot #

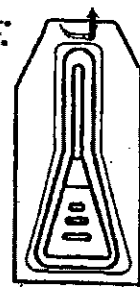
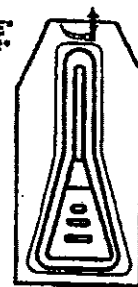
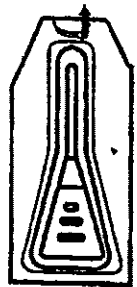
Dog 22
0.023 fl oz
Lot #

FRONTLINE®
Top Spot®

FRONTLINE®
Top Spot®

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Dog 44
0.043 fl oz
Lot #

Dog 44
0.043 fl oz
Lot #

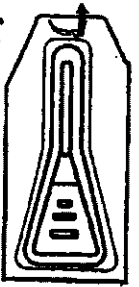
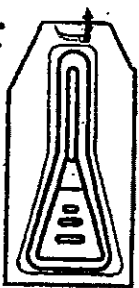
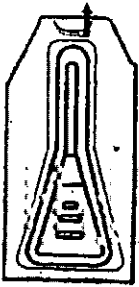
Dog 44
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Lot #

FRONTLINE®
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then peel down.

Dog 88
0.091 fl oz
Lot #

Dog 88
0.091 fl oz
Lot #

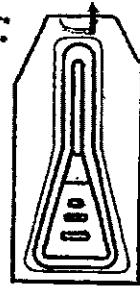
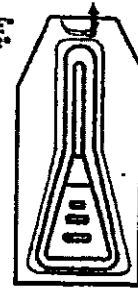
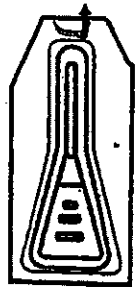
Dog 88
0.091 fl oz
Lot #

FRONTLINE®
Top Spot®

FRONTLINE®
Top Spot®

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FRONTLINE®
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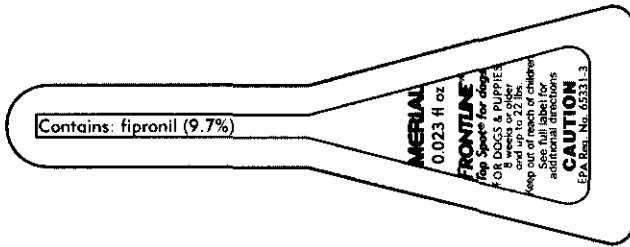
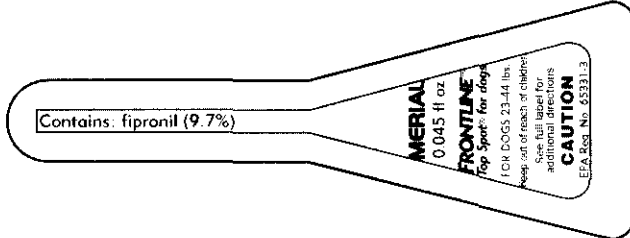
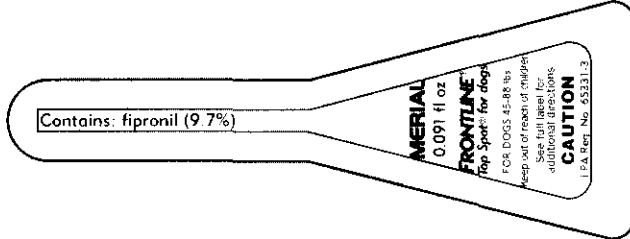
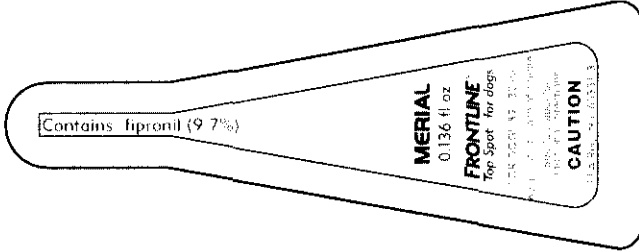
Dog 132
0.136 fl oz
Lot #

Dog 132
0.136 fl oz
Lot #

Dog 132
0.136 fl oz
Lot #

Blister Package

11/13



11

11

13/13



Timothy A. Dotson
Technical Director
Regulatory Affairs North America
Tel: 678-638-3713
Fax: 678-638-3715

3239 Satellite Blvd.
Duluth, GA 30096
Tel: 678 638 3000

March 11, 2004

Ms. Ann Sibold
Team 3, Insecticide Branch
Registration Division (H7505C)
Document Processing Desk (NOTIF)
Office of Pesticide Programs
Room 266A, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202

SUBJECT: Frontline® Top Spot® for Cats, EPA Reg. No. 65331-2
Frontline® Top Spot® for Dogs, EPA Reg. No. 65331-3
Frontline® Plus for Cats, EPA Reg. No. 65331-4
Frontline® Plus for Dogs, EPA Reg. No. 65331-5
NOTIFICATION of Label Revisions Per PR-Notice 98-10

Dear Ms. Sibold:

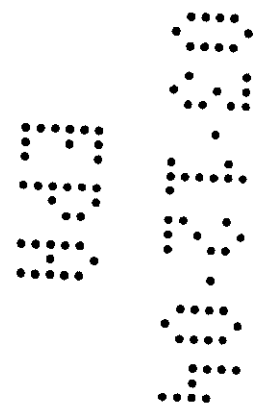
Please find enclosed a NOTIFICATION per PR-Notice 98-10 for revision of the consumer satisfaction guarantee statement located on the carton. Please note that this statement is a 'non-FIFRA' related agreement, if you will, between Merial and the consumer. A portion of this statement is being deleted. Merial's telephone access number will remain the same, providing the consumer with access to Merial's technical services as needed. This statement is similar to the warranty statement on the label, and therefore the Master labels are being submitted by NOTIFICATION only.

Enclosed are copies of EPA Form 8570-1 along with two copies of the revised Master labels for each of the 3X/6X pipette presentations for cats/dogs including all four weight range presentations (dogs only). One copy has been highlighted for ease of review.

Thank you for your assistance. Please call me at 678-638-3713 (email at timothy.dotson@merial.com) if you have any questions regarding this submission.

Sincerely,

Timothy A. Dotson
Technical Director
Regulatory Affairs NA



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