

65331-5

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

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

July 23, 2010

Karen Mardis,  
Sr. Manager, Regulatory Affairs  
Merial, Ltd.  
3239 Satellite Blvd., Bld. 500  
Duluth, GA 30096

Subject: Revised Master Labeling [Child Resistant Packaging (CRP) Wording, Disposal Statement, etc.].

- 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

Submissions dated March 3, 19 & 22, 2010

Dear Ms. Mardis:

The above referenced submissions in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)(7)(a), are acceptable for each product, subject to the following comments and/or terms for conditionally accepted amendments.

**Labeling Comments:**

- All four (4) products have met the requirements for CRP. However, the Agency reserves the right to reevaluate the associated data if (1) an incident report shows any problems in human and (2) an epidemiological evidence indicates a problem once the products reach the marketplace.
- Under Precautionary Statements, revise the statement "Wash hands thoroughly with soap and water after handling" to read "***Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco***".
- Under Warranty, add "***To the extent consistent with applicable law***" to the beginning of the statements "***Sellers make no warranty . . .***".
- Remove the claim from all labels: "Frontline [product name] spreads from the single point of application, rapidly covering the entire [cat][dog] and localizing in the hair, on the surface of the skin **and in the sebaceous glands.**" and, "These glands act as a reservoir, continuously replenishing FRONTLINE TOP SPOT onto the skin and hair coat, so that it keeps working even if the dog gets wet." This claim infers that the product works either subdermally or systemically, and is therefore a claim appropriate only for FDA regulated products.

**Specific Conditions of Acceptance (Cat Products: EPA Reg. Nos. 65331-2 & 65331-4)**

1. The registration for each product is time-limited and expires two years from the date this product is released for shipment bearing the revised language. You must provide the Agency with a projected release for shipment date within 30 days of the date of this letter. The Agency will calculate the expiration date based on the projected release date until an actual release date is provided in writing.
2. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on October 1, 2010. The quarterly reports are due two months after each quarter ends..

Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn: Kimberly Nesci).

**The following is a list of information that must be included in the quarterly reports for each incident:**

EPA Registration Number

Product name (brand name)

Lot #

Where purchased: internet, store, veterinarian

Active Ingredient(s)

Weight range for product

Date on which incident occurred. (mm/dd/yyyy)

State in which the incident occurred. (standard 2 letter abbreviation)

Registrant case #

Species: dog, cat, other (specify)

Breed: (as reported by pet owner)

Age: months or years

Sex: M, F, or neutered

Weight: pounds

Primary Route of Exposure: dermal, oral, other animal, inhalation, other

Body System: neurological, dermatological, GI, respiratory, ocular, other

Major signs noted with separate column for each sign, using standard terminology

Time to Onset: (hours, days)

Treated by veterinarian: yes or no

First time product used: yes or no

Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)

Any known precondition

EPA Severity Code: death, major, moderate, minor

Outcome: died, recovered, still treated, unknown

3. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:

- a. All incidents should be reported including all minor dermal and ocular irritation reports.
- b. Summary table for cats showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
- c. A similar summary table for dogs (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- d. Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- e. A summary table for cats showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- f. A summary table showing the number of cat incidents for each severity code for each pet weight range on the product label (if applicable).
- g. A summary table for cat weight showing number of incidents for each product weight range. This table should show number of incidents in cats weighing less than that product weight range, number of incidents in cats in lower half of weight range, number of incidents in cats in upper half of weight range, and cats weighing more than the product weight range (if applicable).
- h. Table showing number of incidents for each cat breed, where provided.
- i. Table showing number of incidents in cats for each clinical sign.
- j. Table showing number of incidents in cats for each organ system.
- k. Report aggregate incidents, but do not combine moderate and minor incidents.

**Specific Conditions of Acceptance (Dog Products: EPA Reg. Nos. 65331-3 & 65331-5)**

- 1. The registration for each product is time-limited and expires two years from the date this product is released for shipment bearing the revised language. You must provide the Agency with a projected release for shipment date within 30 days of the date of this letter. The Agency will calculate the expiration date based on the projected release date until an actual release date is provided in writing.
- 2. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on October 1, 2010. The quarterly reports are due two months after each quarter ends..

Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn: Kimberly Nesci).

**The following is a list of information that must be included in the quarterly reports for each incident:**

EPA Registration Number

Product name (brand name)

Lot #

Where purchased: internet, store, veterinarian

Active Ingredient(s)

Weight range for product

Date on which incident occurred. (mm/dd/yyyy)

State in which the incident occurred. (standard 2 letter abbreviation)

Registrant case #

Species: dog, cat, other (specify)

Breed: (as reported by pet owner)

Age: months or years

Sex: M, F, or neutered

Weight: pounds

Primary Route of Exposure: dermal, oral, other animal, inhalation, other

Body System: neurological, dermatological, GI, respiratory, ocular, other

Major signs noted with separate column for each sign, using standard terminology

Time to Onset: (hours, days)

Treated by veterinarian: yes or no

First time product used: yes or no

Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)

Any known precondition

EPA Severity Code: death, major, moderate, minor

Outcome: died, recovered, still treated, unknown

3. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:

- a. All incidents should be reported including all minor dermal and ocular irritation reports.
- b. Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
- c. A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.

- d. Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- e. A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- f. A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
- g. A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
- h. Table showing number of incidents for each dog breed.
- i. Table showing number of incidents in dogs for each clinical sign.
- j. Table showing number of incidents in dogs for each organ system.
- k. Report aggregate incidents, but do not combine moderate and minor incidents.

Other Comments:

- Consider limiting the formulations of each product to one basic confidential statement of formula, if applicable. The Agency may require this in the future.
- It is possible that no additional alternate formulations or minor formulation amendments will be approved for this product in the future.
- If the Agency determines that future mitigation measures are necessary for all pet spot-on products, you will be informed, and be expected to comply. If mitigation measures are necessary, the Agency may take appropriate regulatory actions.

Please note that we have approved the amendment for the subject products with the understanding that the labeling for each product is consistent with the Agency's previously approved labels and with the labels for other identical products. Your failure to comply with the above stated conditions nullifies our conditional acceptance of the proposed labeling amendments.

Enclosed with this letter, see our reviews (dated May 26, 2010) of your submitted CRP data. Revise the labeling for each product accordingly to reflect the aforementioned comments, and submit final printed labels to the Agency prior to releasing this product for shipment. See enclosed stamped labels for your record. If you have any questions please contact Dr. B.A. Akinlosotu at (703) 605-0653.

Sincerely,



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

Enclosures

- Labels stamped conditionally approved.
- CRP data evaluation reports (DER)s.

ACCEPTED  
with COMMENTS  
In EPA Letter Dated  
JUL. 23, 2010  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under EPA Reg. No.  
65351-5

**FRONTLINE<sup>®</sup> Plus FOR DOGS**

**3(6) doses**

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

- Fast-acting
- Long-lasting
- Waterproof

**Kills ticks, including those that may transmit Lyme disease**

For DOGS & PUPPIES 8 Weeks of Age and up to 22 lbs

For DOGS 23 to 44 lbs

For DOGS 45 to 88 lbs

For DOGS 89 to 132 lbs

**ACTIVE INGREDIENTS:**  
 Fipronil: 9.8%  
 (S)-methoprene: 8.8%  
**INERT INGREDIENTS: 81.4%**  
**TOTAL: 100%**

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

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Lift Here

FRONTLINE<sup>®</sup> Plus FOR DOGS

PROTOTYPE GRAPHICS

# How to Apply **FRONTLINE®** *Plus* FOR DOGS



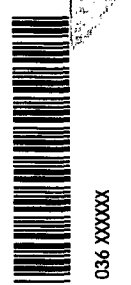
**Step 1. To REMOVE Applicator:**  
Lift and remove the plastic tab to expose foil backing; then peel away the foil. Or use scissors to open.



**Step 2. OPEN Applicator**  
Hold upright with foil side toward you and snap applicator tip.



**Step 3. 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](http://www.FRONTLINE.com)



# FRONTLINE® Plus FOR DOGS

**FRONTLINE® Plus for Dogs is:**

- Fast-acting
- Long-lasting
- Waterproof

**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 that it keeps working even if the dog gets wet.

Fleas, flea eggs & larvae, 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.

**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**

- Kills all life stages of ticks (larva, 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 and other tick-borne diseases

**Lice**

- Rapidly eliminates chewing lice infestations

**Mosquitoes**

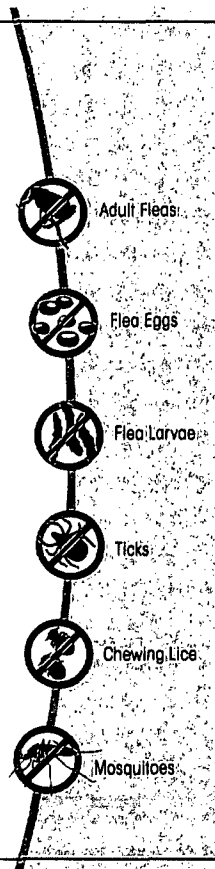
- Kills mosquitoes

**Mites**

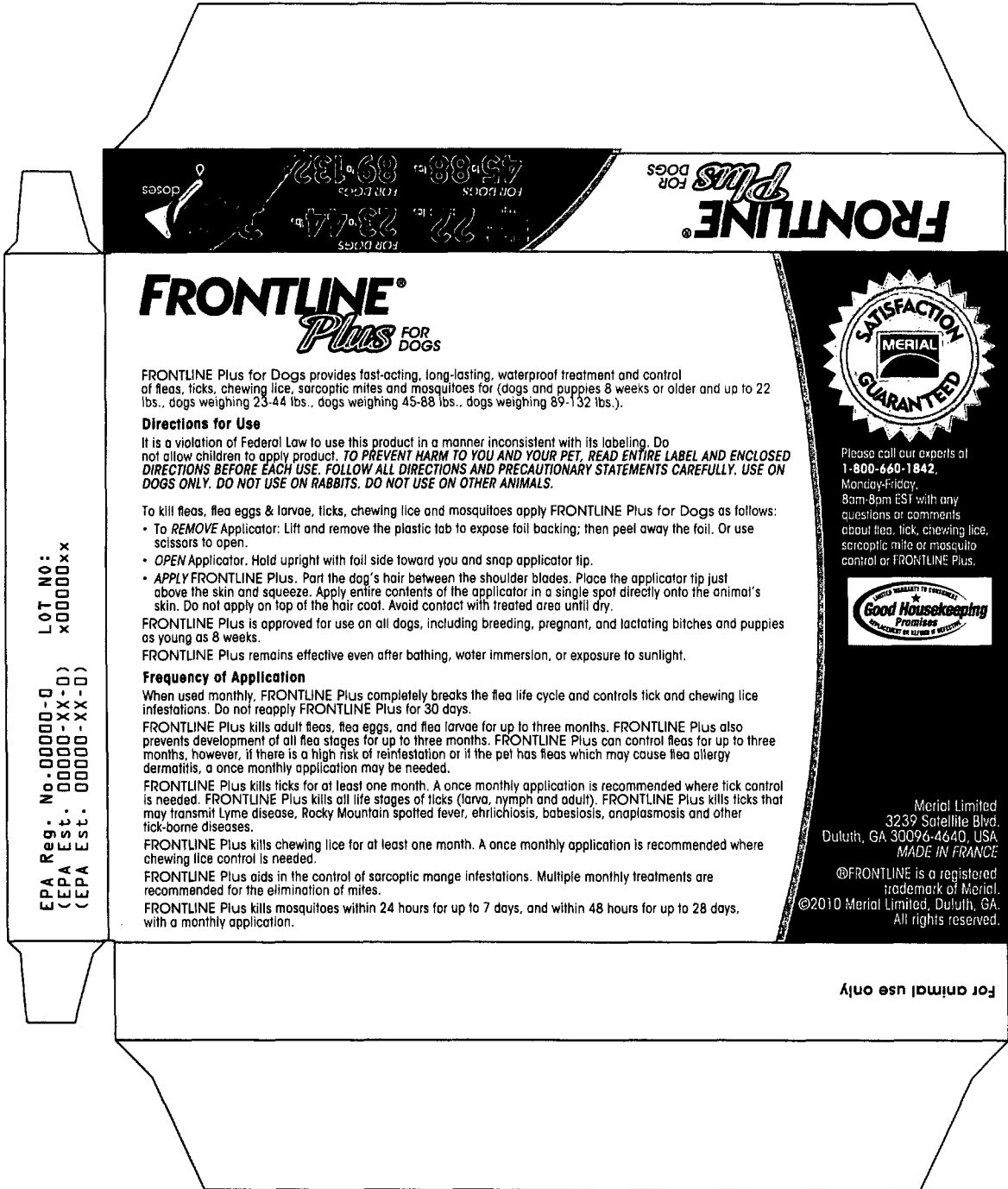
- Aids in control of sarcoptic mange infestations

**FRONTLINE Plus** is approved for use on all dogs, including:

- Breeding, pregnant, and lactating bitches
- Puppies as young as 8 weeks



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# FRONTLINE<sup>®</sup> Plus FOR DOGS

FRONTLINE Plus for Dogs provides fast-acting, long-lasting, waterproof treatment and control of fleas, ticks, chewing lice, sarcoptic mites and mosquitoes 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, flea eggs & larvae, 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 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.

### 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 reinfestation or if the pet 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, 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.

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.



Please call our experts at  
**1-800-660-1842**,  
Monday-Friday,  
8am-8pm EST with any  
questions or comments  
about flea, tick, chewing lice,  
sarcoptic mite or mosquito  
control or FRONTLINE Plus.



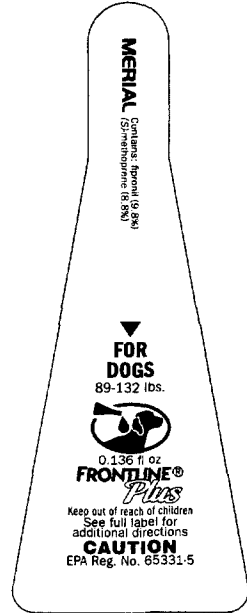
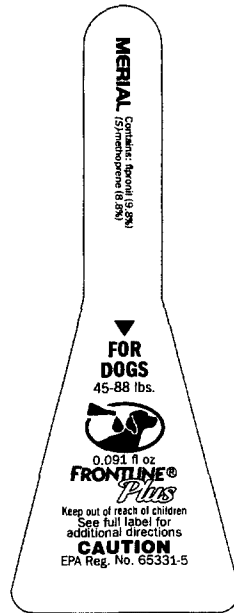
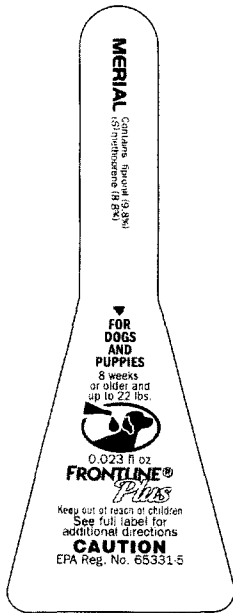
Merial Limited  
3239 Satellite Blvd.  
Duluth, GA 30096-4640, USA  
MADE IN FRANCE

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LOT NO:  
x00000xx

EPA Reg. No. 00000-0  
(EPA Est. 00000-XX-0)  
(EPA Est. 00000-XX-0)

For animal use only



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LINE Frontline Plus FRONTLINE Plus FRONTLINE Plus FROM

**TO REMOVE APPLICATOR:**  
Lift and remove the plastic tab to expose foil backing; then peel away the foil. Or use scissors to open.

0.023 fl oz Lot #

**DOG 22**

LINE Frontline Plus FRONTLINE Plus FRONTLINE Plus FROM

**TO REMOVE APPLICATOR:**  
Lift and remove the plastic tab to expose foil backing; then peel away the foil. Or use scissors to open.

0.045 fl oz Lot #

**DOG 44**

LINE Frontline Plus FRONTLINE Plus FRONTLINE Plus FROM

**TO REMOVE APPLICATOR:**  
Lift and remove the plastic tab to expose foil backing; then peel away the foil. Or use scissors to open.

0.091 fl oz Lot #

**DOG 88**

LINE Frontline Plus FRONTLINE Plus FRONTLINE Plus FROM

**TO REMOVE APPLICATOR:**  
Lift and remove the plastic tab to expose foil backing; then peel away the foil. Or use scissors to open.

0.136 fl oz Lot #

**DOG 132**

# FRONTLINE® Plus FOR DOGS

For **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: .....                | 9.8%          |
| (S)-methoprene .....           | 8.8%          |
| <b>INERT INGREDIENTS</b> ..... | <b>81.4%</b>  |
| <b>TOTAL</b> .....             | <b>100.0%</b> |

### 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

- 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, 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:**

- 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 that 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.

#### 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 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.



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FRONTLINE Plus remains effective even after bathing, water 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 reinfestation or if the pet 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, 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.

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.

**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 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 or advice.

#### 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, Monday-Friday, 8am-8pm EST.

#### PHYSICAL OR CHEMICAL HAZARDS

**COMBUSTIBLE:** Do not use or store near heat or open flame.

#### HOW SUPPLIED

For easy and convenient treatment, FRONTLINE Plus 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. 65331-5

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

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BACK

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# How to Apply FRONTLINE Plus FOR DOGS

**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](http://www.FRONTLINE.com)

Technical area  
No print here  
(except prod. barcode)



BACK

FRONT

## FRONTLINE Plus FOR DOGS

For 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.

|                                |               |
|--------------------------------|---------------|
| <b>ACTIVE INGREDIENTS</b>      |               |
| fenitrothion                   | 9.8%          |
| (S)-methoprene                 | 8.8%          |
| <b>INERT INGREDIENTS</b> 81.4% |               |
| <b>TOTAL</b>                   | <b>100.0%</b> |

**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**
- 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, haemorrhagic fever, ehrlichiosis, babesiosis, 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:**
- 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 that 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.

### 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:

- **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 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.

### 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 reinfestation or if the pet has

# FRONTLINE Plus FOR DOGS

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

- Fast-acting
- Long-lasting
- Waterproof

EPA Reg. No. 65331-5  
EPA Est. 65331-FR-2  
MADE IN FRANCE

Kills ticks, including those that may  
transmit Lyme disease

**ACTIVE INGREDIENTS:**  
Fipronil ..... 9.8%  
(S)-methoprene ..... 8.8%  
**INERT INGREDIENTS:** ..... 81.4%  
**TOTAL:** ..... 100.0%  
[Contains 1-0.091 fl oz (2.68 mL) applicator]  
1 monthly dose

1 **45** to **88** lbs  
2



PIPETTE PLACEMENT SIMULATION

KEEP OUT OF REACH OF CHILDREN  
**CAUTION**

See inside panels  
for FIRST AID and  
PRECAUTIONARY  
statements



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, 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.

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.

**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.

**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 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, Monday-Friday, 8am-8pm EST.

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

**HOW SUPPLIED**  
For easy and convenient treatment, FRONTLINE Plus 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.

Merial Limited  
3239 Satellite Blvd.  
Duluth, GA 30096-4640, USA  
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Part 3-3-10  
Submit

INSIDE PANELS

1  
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

2 For DOGS & PUPPIES  
8 Weeks or Older  
and up to  
**22** lbs

**23** to **89** to  
**44** lbs **132** lbs

# FRONTLINE®

See backside for more...

Some tips and other information

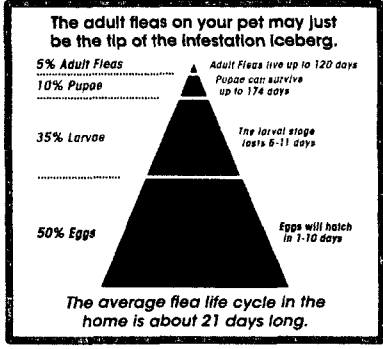


FLEAS: What you need to know



- ✓ To successfully control fleas and ticks, all dogs and cats must be treated with their own dose of FRONTLINE.
- ✓ Apply according to label instructions, ensuring the product is applied to the skin, not on top of the fur and not near the collar. It may be helpful to remove the collar before application, so it doesn't absorb the product.
- ✓ Remember, your pet needs to be dry at the time FRONTLINE is applied and remain dry 24 hours after application.
- ✓ Verify pipette is empty after application (multiple squeezes may be necessary to apply the entire dose).
- ✓ Even indoor pets need flea and tick control because you or other pets in the household may bring fleas into the home. These fleas can lead to a flea infestation.

It can take up to 3 months to get rid of a serious flea infestation because of all of the flea life stages that existed BEFORE you started using FRONTLINE.



Front

Calendar Reminder stickers

Don't forget to re-purchase!

To ensure continued protection of your pets, use these stickers as a reminder to apply and re-purchase FRONTLINE.

After treating your pet for the first time, peel off the sticker and place on your calendar that day.

Place the remaining stickers on your calendar as a reminder to apply FRONTLINE monthly.

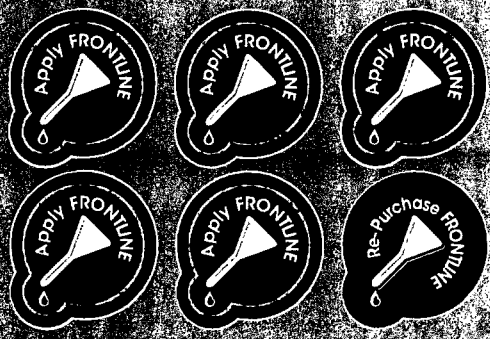
**QUESTIONS?**  
 Contact your veterinarian or call our technical expert at:  
**1-800-660-1842**  
 Monday-Friday, 8am-8pm  
 For more information visit [www.FRONTLINE.com](http://www.FRONTLINE.com)



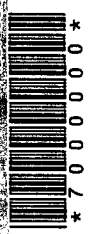
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6 Months use all 6 stickers

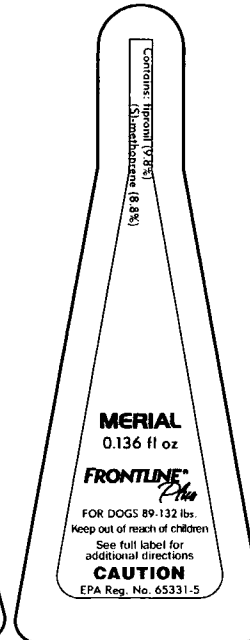
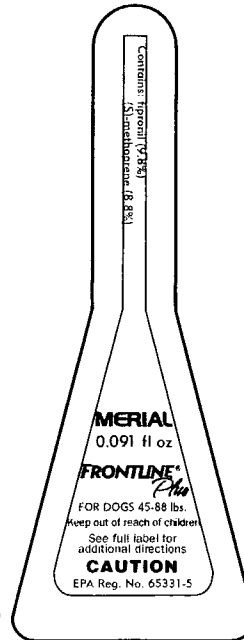
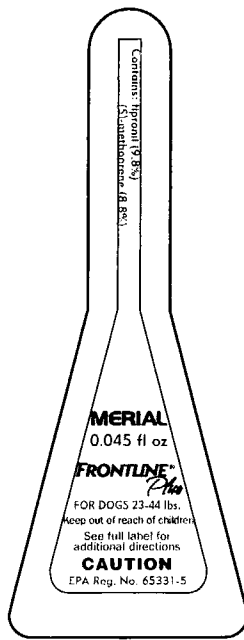
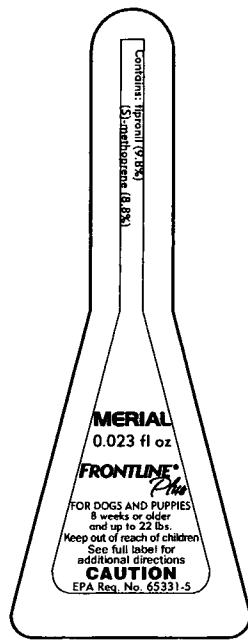
3 Months



037 000000

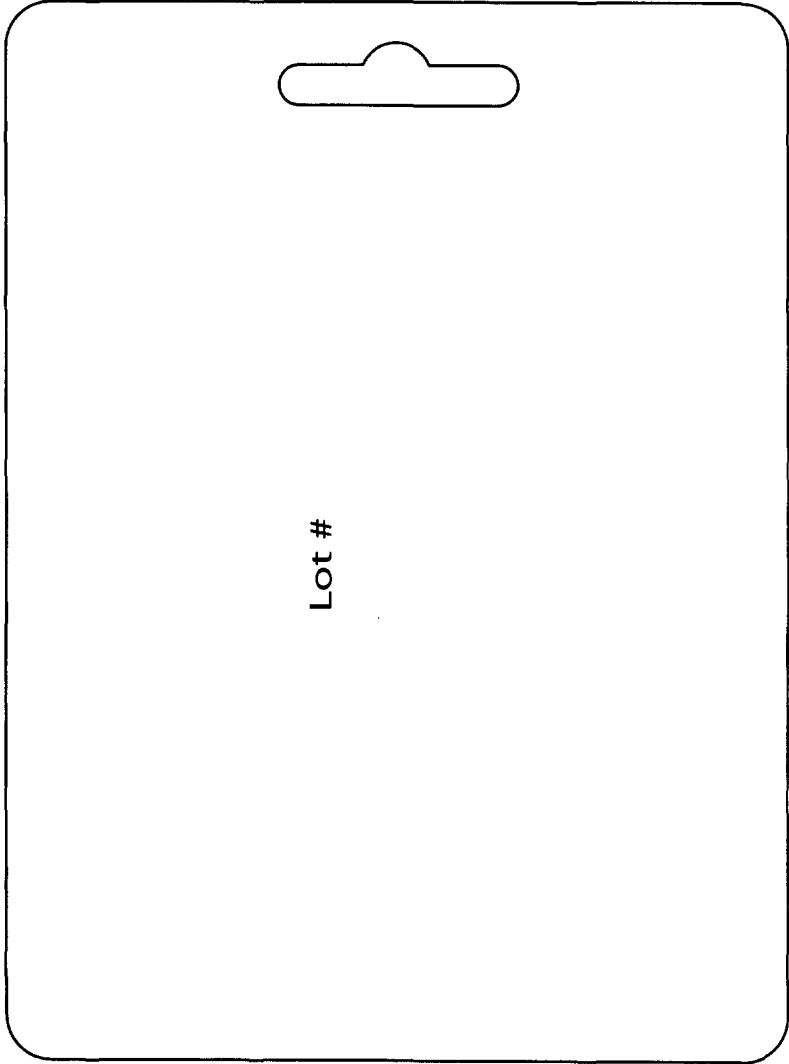


Back with stickers



16/17





Lot #