Ms. April Hawkes Enforcer Products P.O. Box 1060 Cartersville, GA 30120-1060

MAR 30 2004

Dear Ms. Hawkes:

Subject: Amendment - alternate formulation

Enforcer P002-082797-RMP

EPA Registration No. 40849-72

Your Submission Dated January 9, 2004

Your Confidential Statement of Formula (CSF) dated January 9, 2004 has been reviewed and is acceptable.

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable, and a copy of a stamped label is enclosed for your records.

Sincerely yours,

George T. LaRocca Product Manager (13) Insecticide Branch Registration Division (7505)

Enclosure

# **ENFORCER**<sub>®</sub> **P002-082797-RMP**

- Topical Flea & Tick Treatment for Dogs and Puppies six months and older
- Contains [With] Precor®, Vigren® [Insect Growth Regulator (IGR)] or FGR® (Flea Growth Regulator)
  - Prevents Flea Eggs from Developing into Biting Adults for up to 30 Days [3 Months]
- IMPORTANT! [Intended] For Use on Dogs and Puppies 6 Months of Age or Older; Do not use on Cats!

# No Cat Graphic

- For [Use on] Dogs and Puppies Under 30 lbs. [0.03 fl. oz. (1 cc) applicator]
  - Kills and Repels Fleas, Ticks and Mosquitoes for up to 30 Days
    - Kills Fleas Before they Lay Eggs
    - Kills Flea Eggs to Prevent Reinfestation
    - [Number] Convenient, Pre-Filled Applicators
      - Easy and Convenient to Use
    - 3 Month Supply [1 applicator = 1 month treatment]
      - 3 Month Flea & Tick Treatment
    - Once a Month Flea, Tick and Mosquito Treatment
      - 3 Month treatment for dogs under 30 pounds
    - Month 1
- Month 2
- Month 3

(Front or Back)

#### **ACTIVE INGREDIENTS:**

Total .....

MOCCEPTED

# Keep Out of Reach of Children CAUTION

See back panel for [Ingredients and] additional precautionary statements.

MAR 30 2004

Under the Federal Insecticida, Fungicide, and Rodenticide Act, as amended, for the perticide registered under RPA Reg. No. 10.849 - 7.3

Net Contents: 3 - 0.03 fl. oz. (1 cc) applicators [dogs/puppies under 30 lbs.]

[Alternate applicator sizes permissible as long as dosage/ratios are maintained the same. See end of label for examples\*]

EPA Reg. No. 40849-72

EPA Est. 40849-GA-1

# READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS OR PUPPIES. DO NOT USE ON CATS!

#### PRECAUTIONARY STATEMENTS

#### Hazards to Humans & Domestic Animals

CAUTION: Humans: Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling. Domestic Animals Do not use on puppies less than six months of age. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with a mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian IMMEDIATELY. In the event of an emergency, contact the National Animal Poison Control Center at 1-800-345-4735.

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1	It on Skin	•	Take off contaminated clothing.
1	or Clothing:	•	Rinse skin immediately with plenty of water for 15-20 minutes.
1		•	[Call a poison control center or doctor for treatment advice.] (if space available)
١	Have the product conta	iner	or label with you when calling a poison control center or doctor or going for treatment. You may also
ł	contact 1-800-241-565	5 [1-8	300-950-4783 or 1-800-766-7661 or a Poison Control Center] for emergency medical treatment, Monday

[Note: First Aid statement paragraph format may be used if space is limited]

#### **Environmental Hazards**

This product is toxic to fish.

## Physical or Chemical Hazards

[Combustible.] Do not use or store near heat or open flame.

		F SCHEDULE ery 30 days per dog.	
Pet's Name	First Treatment Date	Second Treatment Date (30 Days From 1 <sup>st</sup> )	Third Treatment Date (30 Days From 2 <sup>nd</sup> )

Reminder: I purchased P002-082797-RMP from:

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This product [or product name] prevents eggs from developing into adult fleas for up to 30 days [3 months]. This product [or product name] also kills and repels ticks and mosquitoes for up to 30 days.

#### Do Not Use on Cats!

May be toxic and potentially fatal if applied to or ingested by cats. Cats that actively groom or engage in close physical contact with recently treated dogs may be at risk of serious harmful effects.

Graphics for Each Step

.lternate applicator sizes permissible as long as dosage/ratios are maintained the same. See end of label for examples\*]

- Friday, 9am-5pm EST.

- 1. Remove pre-filled applicator(s) from package and hold in an upright position.
- 2. [Gently press cap to break the seal of the applicator.] [Simply twist cap to break the seal of the applicator.] Open applicator by carefully cutting the top of the tube.
- 3. [Carefully remove the cap.] Position the tip of the applicator on the dog's back between the shoulder blades. Apply half of the contents of the tube (0.5 cc) and proceed with steps 4 and 5.
- 4. Invert the applicator to an upright position and move to the dog's hindquarters. Position the tip of the applicator at the base of the tail and apply the remaining contents of the tube (0.5cc).
- 5. Do not reapply product for 30 days.

[Alternate Packaging Directions]

- 1. Bend at perforation and tear off first month's applicator.
- 2. Hold applicator upright and snap tip back, away from face and body.

Note: DO NOT APPLY this product [or product name] to cats. These flea drops are intended for dogs only!

Although this product [or product name] is applied only between the shoulder blades and at the base of the tail [and in the middle of the back (over 60 lbs)], the dog's skin and hair oils carry the product over the entire body for protection against fleas, ticks and flea eggs. This product [or product name] is most effective when used as part of a total flea and tick management program. Use other [Enforcer] products registered for residential area control of these pests in conjunction with this treatment. [For additional control of fleas in and around the home use [product names] Enforcer Flea Spray for Yards Concentrate and Enforcer Flea Spray for Homes.]

#### STORAGE AND DISPOSAL

Storage: Store in a cool, dry area in a location out of reach of children and pets.

Disposal: If empty: Do not reuse this container [empty applicator]. Place in trash or offer for recycling if available.

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.

Copy:

[Disposal: Do not reuse this container [empty applicator]. Place in trash or offer for recycling if available. Never place unused

product down any indoor or outdoor drain.]

Product Code:		
		ENEO

Made in USA

ENFORCER® PRODUCTS,

A division of Acuity Specialty Products Group, Inc.
P.O. Box 1060

Cartersville, GA 30120-1060

www.enforcer.com

Questions? Call (770) 386-0801, Monday through Friday, 9 am to 5 pm EST [In case of emergency or for product use information, call (phone number) or visit our Web site: (URL)

## [Alternate Language for dogs Over 30 lbs] [E]

[Alternate applicator sizes permissible as long as dosage/ratios are maintained the same. See end of label for examples\*

For [Use on] Dogs and Puppies Over 30 Lbs. [0.03 fl. Oz. (1 cc) applicator]

- 3 Month treatment for dogs Over 30 pounds
- 3 Month Supply [2 applicators = 1 month treatment]

Net Contents: 6 – 0.03 fl. Oz. (1 cc) applicators

- 1. Remove pre-filled applicator(s) from package and hold in an upright position.
- 2. [Gently press cap to break seal of the applicator.] [Simply twist cap to break the seal of the applicator.] Open applicator by carefully cutting the top of the tube.
- 3. [Carefully remove the cap.] Position the tip of the applicator on the dog's back between the shoulder blades. Apply the entire contents of the tube (1 cc) and proceed with steps 4 and 5.
- 4. Open another applicator (following directions provided in steps 1 and 2 above). Position the tip of the applicator at the base of the tail and apply the entire contents of the tube (1 cc).
- 5. Do not reapply product for 30 days.

#### [Alternate Packaging Directions]

- 1. Bend at perforation and tear off first month's applicator.
- 2. Hold applicator upright and snap tip back, away from face and body.

#### [Alternate Language for dogs over 60 lbs] [W]

[Alternate applicator sizes permissible as long as dosage/ratios are maintained the same. See end of label for examples\*]

4 Month Supply [1 applicator = 1 month treatment]

Net Contents: 4 – 3cc applicators

- 1. Remove pre-filled applicator(s) from package and hold in an upright position.
- 2. [Gently press cap to break seal of the applicator.] [Simply twist cap to break the seal of the applicator.] Open applicator by carefully cutting the top of the tube.
- Position the tip of the applicator at the base on the dog's neck. Apply 1/3 of the contents of the applicator.
- 4. Invert the applicator to an upright position and move to the middle of the dog's back. Apply 1/3-2 of the remaining contents of the applicator.
- 5. Invert the applicator to an upright position and move to the base of the dog's tail. Apply the remaining 1/3 of the contents of the applicator.
- 6. Do not reapply product for 30 days.

# [Alternate Packaging Directions]

- 1. Bend at perforation and tear off first month's applicator.
- Hold applicator upright and snap tip back, away from face and body.

#### [Alternate Language for dogs up to 60 lbs] [W]

[Alternate applicator sizes permissible as long as dosage/ratios are maintained the same. See end of label for examples\*]

4 Month Supply [1 applicator = 1 month treatment]

Net Contents: 4 – 2cc applicators [dogs/puppies 31-60 lbs]

Net Contents: 4 - 1 cc applicators [dogs/puppies less than 30 lbs]

- 1. Remove pre-filled applicator(s) from package and hold in an upright position.
- 2. [Gently press cap to break seal of the applicator.] [Simply twist cap to break the seal of the applicator.] Open applicator by carefully cutting the top of the tube.
- 3. Position the tip of the applicator on the dog's back between the shoulder blades. Apply half of the contents of the applicator.
- 4. Invert the applicator to an upright position and move to the dog's hindquarters. Position the tip of the applicator at the base of the tail and apply the remaining contents of the applicator.
- 5. Do not reapply product for 30 days.

#### [Alternate Packaging Directions]

- 1. Bend at perforation and tear off first month's applicator.
- 2. Hold applicator upright and snap tip back, away from face and body.

#### [Alternate Language for dogs of all sizes] [E]

[Alternate applicator sizes permissible as long as dosage/ratios are maintained the same. See end of label for examples\*]

For [Use on] Dogs of All Sizes [0.03 fl oz. (1 cc) applicator]:

- 6 Month treatment for dogs Under 30 pounds [1 applicator = 1 month treatment]
- 3 Month treatment for dogs 30 to 59 pounds [2 applicators = 1 month treatment]
- 2 Month treatment for dogs Over 60 pounds [3 applicators = 1 month treatment]

Drop 1

Drop 2

Drop 3

Drop 4

Drop 5

Drop 6

Net Contents: 6 - 0.03 fl. Oz. (1cc) applicators

#### Alternate Language for dogs of all sizes [E]

[Alternate applicator sizes permissible as long as dosage/ratios are maintained the same. See end of label for examples\*]

For [Use on] Dogs of All Sizes [0.03 fl oz. (1 cc) applicator]:

- 3 Month treatement for dogs Under 30 pounds [1 applicator = 1 month treatment]
- 1.5 Month treatment for dogs 30 to 59 pounds [2 applicators = 1 month treatment]
- 1 Month treatment for dogs Over 60 pounds [3 applicators = 1 month treatment]

Drop 1

Drop 2

Drop 3

Net Contents: 3 - 0.03 fl. Oz. (1cc) applicators

## [Alternate Language for dogs of all sizes [W]

[Alternate applicator sizes permissible as long as dosage/ratios are maintained the same. See end of label for examples\*]

Net Contents: 50 – 1cc applicators

- 1. Remove pre-filled applicator(s) from package and hold in an upright position.
- 2. [Gently press cap to break the seal of the applicator.] [Simply twist cap to break the seal of the applicator.] Open applicator by carefully cutting the top of the tube. [Carefully remove the cap.]
- 3. Apply as directed below.
- 4. Do not reapply product for 30 days.

# [Alternate Packaging Directions]

- 1. Bend at perforation and tear off first month's applicator.
- 2. Hold applicator upright and snap tip back, away from face and body.

# MONTHLY [product name] APPLICATION

Application By Weight	# of 1cc Tubes	Where to Apply	
Dogs up to 29 pounds	One tube	½ tube at base of neck	
		½ tube at base of tail	
Dogs 30 to 59 pounds	Two tubes	I tube at base of neck	
		l tube at base of tail	
Dogs 60 pounds +	Three tubes	1 tube at base of neck	
		1 tube in middle of back	
		1 tube at base of tail	

# [\*Alternate applicator sizes permissible as long as dosage/ratios are maintained the same. Examples:]

DOG WEIGHT	SIZE	WHERE TO APPLY
Less than 15 lbs.	lcc	½ at neck, ½ at tail
16-30 lbs.	1cc	½ at neck, ½ at tail
31-60 lbs.	2cc	½ at neck, ½ at tail
Greater than 60 lbs.	3cc	1/3 at neck, 1/3 at mid-back, 1/3 at tail