1596-146

09/25/2008

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

> OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

SEP 2 5 2008

Mr. Robert Rosenwasser Product Registration The Hartz Mountain Corp. 400 Plaza Drive Secaucus, NJ 07094-3688

SUBJECT: Application for Pesticide Notification (PRN 98-10)

Request Alternate Brand Name(s)

"Hartz InControl Flea & Tick Drops IV for Dogs & Puppies Weighing 15 lbs. and Under"

"Hartz InControl Flea & Tick Drops IV for Dogs & Puppies Weighing 16 to 30 lbs."

"Hartz InControl Flea & Tick Drops IV for Dogs & Puppies Weighing 31 to 60 lbs."

"Hartz InControl Flea & Tick Drops IV for Dogs & Puppies Weighing Over 60 lbs."

"Hartz InControl InControl Advanced 1 Flea & Tick Drops IV for Dogs & Puppies Weighing 15 lbs. and Under."

"Hartz InControl Advanced 1 Flea & Tick Drops IV for Dogs & Puppies Weighing 16 to 30 lbs."

"Hartz InControl Advanced 1 Flea & Tick Drops IV for Dogs & Puppies Weighing 31 to 60 lbs."

"Hartz InControl Advanced 1 Flea & Tick Drops IV for Dogs & Puppies Weighing Over 60 lbs,"

"Hartz UltraGuard Pro IV Flea & Tick Drops for Dogs & Puppies Weighing 4 to 15 lbs."

"Hartz UltraGuard Pro IV Flea & Tick Drops for Dogs & Puppies Weighing 16 to 30 lbs."

"Hartz UltraGuard Pro IV Flea & Tick Drops for Dogs & Puppies Weighing 31 to 60 lbs."

"Hartz InControl Pro IV Flea & Tick Drops for Dogs & Puppies Weighing >60 lbs."

"Hartz UltraGuard Plus IV Flea & Tick Drops for Dogs & Puppies Weighing 4 to 15 lbs."

"Hartz UltraGuard Plus IV Flea & Tick Drops for Dogs & Puppies Weighing 16 to 30 lbs." "Hartz UltraGuard Plus IV Flea & Tick Drops for Dogs & Puppies Weighing 31 to 60 lbs."

"Hartz UltraGuardFlea & Tick Drops IV for Dogs & Puppies Weighing > 60 lbs."

EPA Reg, No. 2596-146 Application Dated July 3, 2008

## Dear Registrant:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated 07/03/08 for the above product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at 703-305-6249 or Owen F. Beeder of my staff at 703-308-8899.

Sincerely,

2

Linda Arrington Notifications & Minor Formulations Team Leader Registration Division (7505P) Office of Pesticide Programs

United States Environmental Protection Weshington, DC 204	<b>•</b> •		stration ndment r	OPP Identifier Number	
Applicatic	on for Pesticide - Se	ection I		· · · · · · · · · · · · · · · · · · ·	
. Company/Product Number 2596-146	2. EPA Product M R. Gebken	R Gebken		oposed Classification	
9. Company/Product (Name) HARTZ Reference 101	<b>РМ#</b> 10	PM# [			
i. Name and Address of Applicant <i>(Include ZIP Code)</i> The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094-3688	(b)(i), my producto: to:	EPA Reg. No.			
Check if this is a new address	Product Name	Product Name SEP 2 5 2008			
	Section - II	· · · · · · · · · · · · · · · · · · ·	·····		
Amendment - Explain below. Resubmission in response to Agency letter dated Notification - Explain below. Explanation: Use additional page(s) if necessary. (For section "Addition of alternate brand names and optional marketing statemer "This notice is consistent with the provisions of PR Notices 98-10 ar labeling or the Confidential Statement of Formula of this product. I u	Agency "Me Too "Me Too Other - E Other - E I and Section II.) Ints per PR Notice 98-10" and EPA regulations at 40 CFR				
to EPA. I further understand that if this notification is not consistent to EIFRA and I may be subject to enforcement action and penalties un	with the terms of PR Notice 98	-10 and 40 CFR 1	52.46, this prod	luct may be in violation	
. Material This Product Will Be Packaged In:					
Child-Resistant Packaging Unit Packaging	Water Soluble Packaging	2. Typ	e of Container		
Yes Yes No	Yes No		Metal Plastic Glass		
* Certification must be submitted	If "Yes" No. pe Package wgt contai		Paper Other (S	pecify)	
. Location of Net Contents Information       4. Size(s) Retr         Label       Container         . Manner in Which Label is Affixed to Product       Lithoar		5. Location o	f Label Directio	ns	
. Manner in Which Label is Affixed to Product Lithogr Paper Stencil	glued				
	Section - IV				
. Contact Point (Complete items directly below for identification	n of individual to be contacte	d, if necessary,	to process this	application.)	
lame Robert Rosenwasser	Title Director, Regulatory Affair	S	1 .	8 No. (Include Area Code) 1800, ext. 7202	
Certifican I certify that the statements I have made on this form and I acknowledge that any knowlinglly false or misleading stat both under applicable law.	all attachments thereto are t	rue, accurate an / fine or imprisor	d complete. ment or	6. Date Application Received <b>(Stamped)</b>	
. Signature	3. Title Director, Regulatory Aff	airs	ر ۲۰۰ ر ر ۲۰۰ ر		
. Typed Name	5. Date	108		۰. ۲	



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4800 REGULATORY AFFAIRS

July 3, 2008

Document Processing Desk (NOTIF) Office of Pesticide Programs (7504P) US Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501

# Attention: Mr. Richard Gebken (PM # 10) **RE: HARTZ Reference 101 EPA Reg. No. 2596-146** Addition of alternate brand names per PR Notice 98-10

Dear Mr. Gebken:

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688 is filing this notification to add new alternate brand names for the product.

The Hartz Mountain Corporation is submitting the following information:

- A completed application (EPA Form 8570-1)and;
- Three copies of the proposed notification label.

"This notice is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR §152.46, and no other changes have been made to the labeling or the confidential statement of formula 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 terms of PR Notice 98-10 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."

If you have any questions or need additional information, please feel free to contact me at (201) 271-4800, ext. 7202 or mailto:<u>rrosenwasser@hartz.com</u>.

Sincerely,

Røbert Rosenwasser Director, Regulatory Affairs

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# Hartz<sup>®</sup> Reference 101

Alternate Brand Names:

Hartz® InControl<sup>TM</sup> Flea& Tick Drops IV [for Dogs (&) (and) (Puppies) (Weighing) (15] lbs and Under)]

Hartz® InControl<sup>TM</sup> Flea& Tick Drops IV [for Dogs (&) (and) (Puppies) (Weighing 16 to 30 lbs)]

Hartz@ InControl<sup>TM</sup> Flea& Tick Drops IW [for Dogs (&) (and) (Puppies) (Weighing) 31 to 60 lbs.)

Hartz@InControl™ Flea& Tick Drops IV [for Dogs (&) (and) (Puppies) (Weighing) Over 60)]

Hartz® InControl Advanced<sup>TM</sup> LFlea& Tick Drops [for Dogs (&) (and) (Puppies) (Weighing) 15 lbs: and Under)

Hartz® InControl Advanced<sup>TM</sup> I Elea& Tick Drops [for Dogs (&) (and) (Puppies) (Weighing) 16 to 30 lbs.)]

Hartz® InControl Advanced™ I Flea& Tick Drops [for Dogs (&) (and) (Puppies) (Weighing) 31 to 60 lbs.)]

Hartz® InControl Advanced™ I Flea& Tick Drops [for Dogs (&) (and) (Puppies) (Weighing) over 60)]

Hartz<sup>®</sup> UltraGuard Pro® IN Flea & Tick Drops [for Dogs (&) (and) (Puppies) (Weighing 4 to 15 lbs.)]

Hartz<sup>®</sup> UltraGuard Pro® IV Flea & Tick Drops [for Dogs (&) (and) (Puppies) (Weighing 16 to 30 lbs)]

Hartz<sup>®</sup> UltraGuard Pro® IV Flea & Tick Drops; for Dogs (&) (and) (Puppies) (Weighing 31 to 60 lbs.)]

Hartz<sup>®</sup> UltraGuard Pro® IV Flea & Tick Drops [for Dogs (&) (and) (Puppies) (Weighing > 60 lbs.)]

Hartz<sup>®</sup> UltraGuard Plus™IV Flea & Tick Drops [for Dogs (&) (and) (Puppies) (Weighing 4 to 15 lbs.)]

Hartz<sup>®</sup> UltraGuard Plus™ IV Flea & Tick Drops [for Dogs [(&) (and) (Puppies) (Weighing 16 to 30 lbs.)]

Hartz<sup>®</sup> UltraGuard Plus™ IV Flea & Fick Drops [for Dogs [(&) (and) (Puppies) (Weighing 31 to 60 lbs)]

Hartz<sup>®</sup> UltraGuard Plus™ IV Flea & Tick Drops [for Dogs [(&) (and) (Puppies) (Weighing > 60.1bs.)]

IMPORTANT Intended for use on Dogs DO NOT USE ON CATS

(for Dogs and Pupies Over 60lbs.) (for Dogs and Pupies 31lbs. to 60lbs.)

Optional/alternate text is shown in parentheses or brackets; new text is highlighted page 1 of 8

(for Dogs and Pupies Over 30lbs.) (for Dogs and Pupies 30lbs. and Under) (for Dogs and Pupies 16lbs. to 30lbs.) (for Dogs and Pupies 15lbs. and Under)

#### **Optional Copy**

(3 Month supply, 1<sup>st</sup> Dose, 2<sup>nd</sup> Dose, 3<sup>rd</sup> Dose) (3 Months Protection- First Month, Second Month, Third Month) (triple pack)
(1 Month Supply) (6 Month Supply) (12 month Supply) (Value Pack)
(Advanced Care)
(Advanced Flea and Tick [ and Mosquito] Topical Treatment)

## KEEP OUR OF REACH OF CHILDREN CAUTION: SEE BACK PANEL FOR INGREDIENT STATEMENT AND ADDITIONAL PRECAUTIONARY STATEMENTS

Net Contents:-

(3 tubes, 0.65 cc, 0.02 fl oz each; 1.95 cc, 0.06 fl oz total)

(3 tubes, 1 cc, 0.03 fl oz each; 3 cc, 0.09 fl oz total)

(3 tubes, 2 cc, 0.06 fl oz each; 6 cc, 0.18 fl oz total)

(3 tubes, 3 cc, 0.10 fl oz each; 9 cc, 0.30 fl oz total)

[Net Contents: Three 1cc (2cc) Tubes] (1 tube) (12 Tubes)

(Note To EPA- Package contents vary from 1 tube to 150 tubes. Contents statements will vary accordingly.)

BACK PANEL Mandatory Copy

(Note to EPA- Placement of Ingredient Statement previously approved- optional front or back panel depending on box design)

ACTIVE INGREDIENTS:
Permetrhrin (CAS# 52645-53-1)
(S)-Methoprene (CAS# 40596-69-8)
OTHER INGREDIENTS:

By Weight (Nom.) 45.0% 2.9% 52.1%

READ ENTIRE LABEL BEFORE USE. USE ONLY ON DOGS OVER 6 MONTHS OF AGE.

For use on dogs and puppies only.

Use ONLY on dogs or puppies over 6 months of age. DO NOT USE ON CATS OR OTHER ANIMALS.

### DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

(FOR USE ON 0.65 cc OR 1 cc TUBE PACKAGES) (less than 30 pounds, 15 lbs. and under, 16 lbs. to 30 lbs.)

- 1. Use ONLY on dogs or puppies over 6 months of age. DO NOT USE ON CATS OR OTHER ANIMALS.
- 2. Remove one applicator tube from package and hold in an upright position.

3. Pull off cap. Turn the cap around and place on top of tube.

[3. simply press (twist) cap down to break the seal of tube]

[3. Hold bottom of tube with one hand. With other hand, remove cap and snap off tip.]

[3. Hold bottom of tube with one hand. With other hand, snap cap off.]

4. Remove cap carefully. Position the tip of the tube on the dog's back between the shoulder blades and squeeze out the contents of the tube.

5. Repeat every month. (Repeat ever 30 days if necessary).

(FOR USE ON 2 cc OR 3 cc TUBE PACKAGES) (30 pounds and larger, 31 lbs. to 60 lbs., over 60lbs.)

- 1 Use ONLY on dogs or puppies over 6 months of age. DO NOT USE ON CATS OR OTHER ANIMALS.
- 2 Remove one applicator tube from package and hold in an upright position.
- 3 Pull off cap. Turn the cap around and place on top of tube.

[3. simply press (twist) cap down to break the seal of tube]

[3. Hold bottom of tube with one hand. With other hand, remove cap and snap off tip.]

[3. Hold bottom of tube with one hand. With other hand, snap cap off.]

4. Remove cap carefully. Position the tip of the tube on the dog's back between the shoulder blades and squeeze (out half) (approximately half) (tube to apply one-half) the contents (of the tube) (from the tube to the dog).

5. Invert the applicator tube upright and go to the dog's tail. Position the tip of the tube at the base of the tail and apply the remaining contents of the tube to the base of the dog's tail.

6. Repeat every month. (Repeat every 30 days if necessary).

ALTERNATE PACKAGING DIRECTIONS- for use in warehouse club packaging. This product contains 6 monthly dosages, each (1 cc) For Dogs Over 30Lbs.

1. Use ONLY on dogs or puppies over 6 months of age. DO NOT USE ON CATS OR OTHER ANIMALS.

2. Remove one applicator tube from package and hold in an upright position.

3. Pull off cap. Turn the cap around and place on top of tube.

[3. simply press (twist) cap down to break the seal of tube]

[3. Hold bottom of tube with one hand. With other hand, remove cap and snap off tip.]

[3. Hold bottom of tube with one hand. With other hand, snap cap off.]

4. Remove cap carefully. Position the tip pf the tube on the dog's back between the shoulder blades and squeeze out the contents (of the tube) (from the tube to the dog).5. Remove second applicator tube from package and hold in an upright position.

6. Pull off cap. Turn the cap around and place on top of tube.

[6. simply press (twist) cap down to break the seal of tube]

[6. Hold bottom of tube with one hand. With other hand, remove cap and snap off tip.]

[6. Hold bottom of tube with one hand. With other hand, snap cap off.]

7. Remove cap carefully. Invert the applicator tube upright and go to the dog's tail. Position the tip of the tube at the base of the tail and apply the contents of the tube to the base of the dog's tail.

8. Repeat every month. (Repeat every 30 days if necessary).

STORAGE AND DISPOSAL: Do not contaminate water, food or feed by storage and disposal. Store in a cool, dry place. Do not re-use empty tube. Wrap and discard in trash.

PRECAUTIONARY STATEMENTS- HAZARDS TO HUMANS

Caution: Causes eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

HAZARDS TO DOMESTIC ANIMALS: CAUTION: DO NOT USE ON CATS.

Cats which come in close physical contact with recently treated dogs may be at risk of an adverse reaction. To minimize the chance of an adverse reaction, cats should be separated from the recently treated dog for a minimum of 6 hours. Do not use on puppies less than six months old. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing animals. Sensitivity, such as slight transient irritation or hair loss at the site of application, may occur after using ANY pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rise with large amounts of water. If signs continue, consult a veterinarian immediately.

ENVIRONMENTAL HAZARDS: This product is toxic to fish.

FIRST AID: If in eyes: Flush eyes with plenty of water. Call a physician if irritation persists.

© The Hartz Mountain Corporation, Secaucus, NJ 07094 and St. Thomas, Ontario, N5P 3W7 Canada

EPA Reg. No. 2596-146 EPA Est. No. 2596.-NJ-1

#### **Optional Copy**

(for Dogs and Puppies Over 60 lbs.) (for Dogs and Puppies 31 lbs. to 60 lbs.) (for Dogs and Puppies Over 30 lbs.) (for Dogs and Puppies 30 lbs. and Under) (for Dogs and Puppies 16 lbs. to 30 lbs.) (for Dogs and Puppies 15 lbs. and Under)

prevents (flea) (and mosquito) eggs from hatching (for 30 days) (I month) (4 weeks) kills (flea) (and mosquito) eggs before they hatch

prevents re-infestation for (1 month) (30 days) (4 weeks)

kills flea eggs (and mosquito) (and larvae)

kills hatching eggs

contains an insect growth regulator

contains an adulticide

stops the flea and tick (and mosquito) life cycle

kills all stages of (the) (adult) flea(s) (and mosquito) (life cycle)

kills the Rocky Mountain Wood Tick, which may carry Rocky Mountain Spotted Fever Kills and Repels the Deer Tick, which may carry Lyme Disease (a vector of Lyme disease)

(the major carrier of human and canine Lyme Disease)

Controls (Kills) (Repels) (lasts) (Works) (Protects) up to 30 days (1 month) (4 weeks) Kills and Repels Mosquitoes (Continuous Protection)

Convenient, Easy to use applicator

Easy (simple) to use (Handle) (Apply)

Spreads Naturally with Dog's movement (skin and hair oils)

90% control of fleas and ticks in 48 hours (2 days)

Repels 95% of Ticks within 3 days (72 hours)

Repels 90% of fleas within 3 days (72 hours)

No Mess

**Disposable Applicator** 

Apply to One Spot (two spots) for Head to Tail (Total Body) Flea and Tick (and Mosquito) Protection (Control)

Apply to One Spot- spreads over the dog's complete body (from head to tail) through the natural motion of the animal.

This product contains three monthly doses (one monthly dose), each (2cc) (1cc)

One tubes gives 30 days protection Flea control for Dogs with (PRECOR®) (vIGRen<sup>™</sup>) Insect Growth Regulator (IGR) Satisfaction guaranteed Money back guarantee Guaranteed to Work\*

\*If not completely satified, return unused portion for a full refund. (Precor®) (and) (vIGRen<sup>TM</sup>) (is a) (are) registered trademark(s) of Wellmark Intl.

Hartz Control Pet Care System products are designed to complement each other in an integrated program for flea & tick management. To assure proper treatment, we recommend use of only Hartz Control Pet Care system products.

This product contains three monthly dosages, each (3 cc) (2 cc) (1 cc) (0.65 cc)

[(As with all flea and tick product, they are) (Hartz Ref. 101 is) most effective when used as part of a total program aimed at reducing fleas and ticks (and mosquito) in the dog's environment.] Be sure to treat the animal's bedding and surroundings with products registered for these uses, such as the Hartz Control Pet Care System line. [the Hartz Ref. 101 contains both (an insecticide to kill adult fleas and ticks (and mosquitoes) and an insect growth regulator (IGR) to kill flea (and mosquito) eggs before they hatch.) (a powerful, effective insecticide which kills adult fleas and ticks (and mosquitoes), and a long lasting insect growth regulator which prevents flea (and mosquito) eggs and larvae from maturing into adults.)] (Adult fleas spend virtually all of their time on hour pet, but they product vast numbers of eggs which drop pff the pet and develop in the environment.) ( Once fleas are apparent on your pet, there is already an infestation of their pre-adult stages in your home.) (Normal insecticides will not kill the flea eggs. Bu the Hartz Reg. 101 is designed to kill both the adult flea (and mosquito) eggs and larvae, there by breaking the flea (and mosquito) life cycle.) (the repellent will also break the tick life cycle by killing adult ticks, including the Feet Tick, which may carry Lyme disease, and the Rocky Mountain Wood Tick, which may carry Rocky Mountain Spotted Fever.)

(One Spot<sup>™</sup> provides relief from flea infestations for one month by controlling and preventing fleas on your dog and puppy. Adult fleas can live on your pet while also producing vast numbers of eggs which drop off your pet and develop in the surrounding environment. One Spot<sup>™</sup> kills the adult flea, its eggs and larvae, thereby breaking the flea life cycle. One Spot breaks the tick life cycle by killing ticks, including the Rocky Mountain Wood Tick and the Deer Tick (the major carrier of human and canine Lyme Disease). One Spot<sup>™</sup> also kills and repels mosquitoes, a major carrier of canine heartworms.)

After application, through its natural movement, your pet's skin and hair oils carry One Spot<sup>TM</sup> over the pet's body for protection against fleas, ticks (mosquitoes), flea eggs and larvae. Initially, to kill existing adult flea populations, you may need to treat the home, pet's bed and yard with traditional flea products such as home sprays, foggers and/or yard

& kennel spray. One Spot<sup>™</sup> can be used in conjunction with the entire Control Pet Care System® product line.

To help remind you when you last applied treatment, simply write in the date when each dose is applied. First Dose\_\_\_\_\_\_ Second Dose\_\_\_\_\_\_ Third Dose

Visit our Website www.hartz.com Hartz. Every Pet's Best Friend

(If not completely satisfied with this product, return it to place of purchase with your receipt for a full refund.)

(For more information about [Brand Name] products call 1-800-XXX-XXXX weekdays from 8 am to 8 pm EST.

(For more information, (or in case of emergency) help at any step), call our Flea and tick experts at (telephone number), (time)

If not completely satisfied, return unused portion for a full refund.

**OPTIONAL COPY #1** 

B- Protect Your Pet- withone of the control on-animal products such as Conditioning Shampoo, dip, Powder or Spray to kill fleas and ticks living on your pet. Use a Control product containing vIGRen®, an Insect Growth Regulator (IGR) to also stop hatching eggs from developing into biting adults.

Step B-PROTECT YOUR PET with a Control repellent or flea and tick collar to keep fleas and ticks fro reinfesting your pet. The control Pet Care System Ultimate Flea Collar<sup>™</sup> will also prevent flea eggs from hatching.

Step C- TREAT YOUR HOME, both indoors and outdoors, with Control Pet Care System Home Flea & Tick Killer or Fogger with vIGRen and Control Pet Care System Yard and Kennel Spray to protect your entire home and guard against reinfestation. The Control Pet Care System Flea Trap will also serve to help break the flea life cycle by killing fleas in hard-to-reach areas in your home.

Be sure to read full directions and precautions on the label of each product you use. For more information or help at any step, call our flea and tick experts at 1-800-275-1414, weekdays 9am-5pm EST.

7/3/08

Rabon® is a registered trademark for Tetrachlorvinphos vIGRen® is a registered trademark for Wellmark Intl.

**OPTIION COPY #2** 

The Stress-Free System for Eliminating Fleas and Ticks

On Animal Protection

Relief for your

Use Releve Pet Protection System conditioning Shampoo, Dip, Spray or Powder to kill fleas and ticks living on your pet.

#### Repellent

Keep fleas and ticks off your pet

Prevent any more fleas and ticks from coming onto your pet by spraying your pet with Releve Pet Protection System Repellent for Dogs or Repellent for Cats.

**Continuous Protection** 

Long-term protection for your pet

Keep fleas and ticks from reinfesting your pet with Releve Pet Protection System 7 Month Flea & Flea Egg Collar with vIGRen®, which will prevent flea eggs from hatching and Rabon® to kill adult fleas and ticks.

Home & Yard

Protect your home and yard

Kill fleas and ticks around your home with Releve Pet Protection System Carpet Powder, Yard and Kennel Spray, Home Flea & Tick Killer and Home Fogger.

Remember to always read each product label and follow the directions carefully.

Rabon® is a registered trademark for Tetrachlorvinphos vIGRen® is a registered trademark for Wellmark Intl.