



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

October 31, 2012

Ms. Sharon M. Johnston Regulatory Consultant for W.F. Young, Inc. c/o RegGuide Pesticide Regulatory Services 509 Tower Valley Drive Hillsboro, MO 63050-1216

Subject:

Amended Labeling; Addition of Alternate Packaging (Bag-On-Valve)

WFY0301, EPA Reg. No. 1543-15

Your Submission Dated July 30, 2012 & E-Mail Resubmission Dated October 25, 2012

Dear Ms. Johnston:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable with the following label revision provision(s):

General Comment(s):

- 1. Delete all text throughout the label marked with "strikethrough."
- 2. To facilitate inclusion of additional label changes from the revised RED for permethrin (May 2009), it is suggested that you make the following changes:
 - Insert the following statement prominently on the front panel of the subject product packaging (in bold) to read "DO NOT USE ON CATS"
 - Revise the existing 4th bulleted use restriction within the revised "USE RESTRICTIONS" subsection to read "DO NOT USE ON CATS OR KITTENS. <u>Do not treat cats or their bedding</u>. <u>This product may be toxic or potentially fatal if applied to or ingested by cats or kittens."</u>
 - It is suggested that all cat warning labels have language placed within a shaded text box within the "HAZARDS TO HUMANS AND DOMESTIC ANIMALS" subsection. The coloring of the box and text will be such to provide a contrasting color to other label text. In addition, each label must include at least one (1) cat slash icon which may be in the shaded box or in other areas on the subject label. The shaded box must contain the following:

DO NOT USE ON CATS OR KITTENS. **May be toxic or potentially fatal if applied to or ingested by cats.** Accidental application to cats and/or grooming a recently treated dog may result in tremors and/or uncoordinated muscle movements. If this occurs, immediate veterinary care should be provided.

Please note that these statements are being suggested for ALL permethrin pet products, including spot-on products, because permethrin is known to be very toxic to cats.

Optional Marketing Statements section comment(s), top of page 1 of 11:

3. To facilitate inclusion of required label language from the REDs for pyrethrins and piperonyl butoxide (updated label table for pyrethrins/piperonyl butoxide combo products) and the revised RED for permethrin (May 2009), within the 4th optional marketing statement you must replace the word "... horses]" with the words "... horses, ponies and foals (over 12 weeks of age)]" Net Contents section comment(s), bottom of page 1 of 11:

4. To facilitate inclusion of required label language from Chapter 17, Section III of the Agency's Label Review Manual, the net contents for pressurized products must be expressed as pounds and ounces pursuant to 40 CFR §156.10(d)(3), while liquid formulations must be expressed in terms of liquid measure (fluid ounces) pursuant to 40 CFR §156.10(d)(2). As such, you must revise the "Net Contents" on the subject label to read:

"Net Contents __ fluid ounces

{Net Contents expression for Bag-On-Valve packaging}

Net Contents ___ fluid ounces (__ mL)
Net Contents ___ pounds (__ grams)"

Directions for Use, Subsection-Specific comment(s), middle of page 3 of 11:

5. To facilitate inclusion of required label language from the REDs for pyrethrins and piperonyl butoxide (updated label table for pyrethrins/piperonyl butoxide combo products), the revised RED for permethrin (May 2009), and to maintain consistency throughout the subject label, you must revise "HORSES AND PONIES (OVER 12 WEEKS OF AGE)" to read "HORSES, PONIES, AND FOALS (OVER 12 WEEKS OF AGE)"

Additional Alternate Bullet Points section comment(s), middle of page 11 of 11:

6. To facilitate inclusion of required label language from the REDs for pyrethrins and piperonyl butoxide (updated label table for pyrethrins/piperonyl butoxide combo products) and the revised RED for permethrin (May 2009), you must revise the 17th additional alternate bulleted point to read "[For use on horses, ponies and foals (over 12 weeks of age)]"

Should you wish to add/retain a reference to the company's website on your label, please be aware that the website becomes labeling under FIFRA and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under section 12(a)(1)(E) of FIFRA. 40 CFR §156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not be substantially differ from those claims approved through the registration process. Therefore, should the Agency find, or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to EPA's Office of Enforcement and Compliance Assurance (OECA). As an alternative, you may refer consumers to the company's phone number or e-mail address.

Copies of your label stamped "Accepted with Comments" as well as the product chemistry review completed as part of this action are enclosed for your records. Please submit two (2) copies of the final printed labeling, incorporating the above changes, before releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA. Your release for shipment of the product bearing amended labeling constitutes accepting of these conditions.

If you have any questions about this label review, please contact Mr. Carmen Rodia at (703) 306-0327 or via e-mail at <u>Rodia.Carmen@epa.gov</u>.

Sincerely Yours,

Richard J. Gebken Product Manager (10)

Insecticide Branch

Registration Division (7504P)

Land L. Cell

Enclosures:

Label Stamped "Accepted with Comments," dated October 31, 2012 Product Chemistry Review, dated October 10, 2012

001543-000015 D468583

WFY0301

[Weatherproof Insecticide & Repellent]

[The Horse World's Most Trusted Name® [Since 1892]]

[Field tested and proven effective]

[Kills and repels [biting and nuisance flies, gnats, mosquitoes on horses] [for up to 17 days]]

[Kills and repels biting and nuisance flies, ticks that may carry Lyme Disease and mosquitoes including the Culex species which has been known to transmit West Nile Virus]

[Long-lasting repellency that protects and stays active for up to 17 days]

[Weatherproof formula [binds to the hair shaft to repel and protect from bugs, sun, sweat, water, dust and dirt] [for up to 17 days]]

[[Sun] [Sweat] [water and rain] resistant formula [that produces a shine that shields]]

[Stays active for up to 17 days]

[17-day [waterproof] [pasture] protection]

[Extends repellence for 17 days [with Bug Block® Technology]] -

[Bug Graphics: fly, mosquito, tick, gnat]

[Weather Graphics]

[Kills [& Repels] more than 70 species]

[[With] UltraBond Technology]

ACCEPTED
With COMMENTS
In EPA Letter Dated:

Under the Federal Insecticide, Fungicide and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No:

ACTIVE INGREDIENTS:

Permethrin*	0.50%
Pyrethrins	0.10%
Piperonyl Butoxide**	
OTHER INGREDIENTS:	98.40%
TOTAL:	100.00%

^{*}cis/trans ratio: Min. 35% (+/-) cis and Max. 65% (+/-) trans.

{Additional alternate bullet points listed at end of label}

KEEP OUT OF REACH OF CHILDREN CAUTION

See Back/Side Label Panel for Additional Precautionary Statements

Net	Contents	

^{**(}butylcarbityl)(6-propylpiperonyl) ether and related compounds

MASTER LABEL

October 25, 2012

READ ENTIRE LABEL BEFORE EACH USE ON ANIMAL USE - USE ONLY ON HORSES, PONIES, FOALS (Over 12 Weeks of Age), DOGS AND PUPPIES (Over 12 Weeks of Age)

DIRECTIONS FOR USE

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

USE RESTRICTIONS

- Do not apply as a space, broadcast or spot treatment to indoor surfaces at residential sites.
- Do not store near or use with oxidizing agents. This product is not for use on foals less than 12 weeks of age. This product is not for use on puppies less than 12 weeks of age. This product is not for use on animals intended for human consumption.
- All outdoor applications must be limited to spot or crack-and-crevice treatments only. Except when applying directly to animals, 1) do not allow adults, children or pets to enter the treated area until sprays have dried; 2) do not apply this product in a way that will contact adults, children or pets either directly or through drift. Exit area immediately and remain outside the treated area until sprays have dried. Remove or cover exposed food and drinking water before application. Remove or cover dishes, utensils, food processing equipment and food preparation surfaces or wash them before use. Do not wet articles to point of runoff or drip. Do not use treated article until spray has dried. Remove pets, birds and cover fish aquariums before spraying. Application is prohibited directly into sewers or drains or to any area like a gutter where drainage to sewers, storm drains, water bodies or aquatic habitat can occur. Do not allow the product to enter any drain during or after application.

HOLD CONTAINER UPRIGHT. SHAKE WELL BEFORE USING.

Spray or wipe-on. Protect your horses and dogs. Ready to use. No mixing necessary. This water-based formulation may be applied directly with spray applicator or as a wipe-on.

17-day weatherproof formula provides long-lasting repellency and protection from biting and nuisance flies, gnats, ticks and mosquitoes. This unique formula also contains multiple sunscreens and coat conditioners including Aloe and Lanolin and it is pleasantly scented with Citronella.

October 25, 2012

HORSES AND PONIES (Over 12 Weeks of Age):

Kills and repels biting and nuisance flies, gnats, mosquitoes and ticks for up to 17 days. Including Horse Flies, Stable Flies, Face Flies, Horn Flies, Deer Flies, House Flies, Black Flies, Cluster Flies, Sciarid Flies, Gnats, Midges, Punkies, No-See-Ums, Deer Ticks, Lone Star Ticks, Chiggers, American Dog Ticks, Brown Dog Ticks, Gulf Coast Ticks, Fleas and Lice.

USE AS A WIPE OR A SPRAY: This product may be applied either as a wipe or as a spray. When applying as a wipe or on the horse's face, always use a soft cloth. First, brush animal to remove excess dirt and dust. Spray or wipe horse's entire body while brushing against the lay of the coat to ensure adequate coverage. Avoid getting spray into horse's eyes, nose or mouth. Do not wet skin or apply to the point of dripping or exceed two ounces per application. Reapply every 7- to 10 days under normal conditions for initial applications. As protection builds, reapply every 12 to 17 days as needed. Also, reapply each time animal is washed or exposed to heavy rain for best results. After application, brush thoroughly to bring out bright sheen on the coat.

DOGS AND PUPPIES (Over 12 Weeks of Age): Kills and repels fleas, ticks (that may carry Lyme Disease), mosquitoes and lice on dogs. Also kills and repels fleas, ticks, mosquitoes and lice around premises. Cover animal's eyes with hands. With a firm stroke to get a proper spray mist, spray head, ears and chest until damp. With soft cloth, rub into face around mouth, nose and eyes. Then spray neck, middle and hind quarters, finishing legs last. For best penetration of spray to the skin, direct spray against natural lay of the hair. On long haired dogs, rub against the lay of the hair, spraying the ruffled hair directly behind the hand. Make sure spray thoroughly wets ticks. During the flea season, retreat every 3-4 weeks if necessary. Kills fleas, ticks and lice on dogs and provides up to 28 days protection from reinfestation. Sensitivities may occur after using ANY pesticide product on pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals or animals on medication.

DOGS SLEEPING QUARTERS

Spray around baseboards, windows, door frames, wall cracks and localized areas of floors. The pet's bedding areas should be sprayed. Spray old bedding or replace with fresh bedding.

MASTER LABEL

October 25, 2012

USE AS A PREMISE SPRAY: Kills insects on contact such as: Carpenter Bees, American Cockroaches, Asian Cockroaches, Australian Cockroaches, Brown Banded Cockroaches, German Cockroaches, Oriental Cockroaches, Smokey Brown Cockroaches, Black Widow Spiders, Cellar Spiders, Fire Ants, Carpenter Ants, Pharaoh Ants, Foraging Ants, Grain Mites, Clover Mites, Beetles (including Carpet, Flat Grain, Flour, Cigarette, Confused Flour, Drugstore, Lesser Grain Borer, Merchant Grain, Sawtoothed Grain, Warehouse, Red Flour, Ground, Elm Leaf and Rice Weevils), Palmetto Bugs, Water Bugs, Cadelles, Indian Meal Worms, Sowbugs, Boxelder Bugs, Earwigs, Pillbugs, Firebrats, Silverfish, Clothes Moths, Booklice, Centipedes, Millipedes, Crickets, Earwigs, Scorpions, flying moths (including Almond, Chocolate, Tobacco, Indian Meal and Angoumois Grain and other flying moths). Spray in areas where insects congregate. Apply at a rate of 1 gallon per 1000 sq. ft. [1 quart [32 oz] per 250 sq. ft.] [1 oz per 8 sq. ft.]. Direct spray to contact insects for rapid knockdown and kill. Spray around door facings and screens to render area unattractive to insects. This will help to repel insects and prevent entrance into building.

STORAGE AND DISPOSAL

Pesticide Storage: Store in a cool, dry (preferably locked) place that is away from heat or open flame, in an area that is protected from freezing (above 32°F) and is also inaccessible to children and animals.

Pesticide Disposal And Container Handling: Non-refillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

{Alternate Storage and Disposal instructions for refillable containers}

STORAGE AND DISPOSAL

Pesticide Storage: Store in a cool, dry (preferably locked) place that is away from heat or open flame, in an area that is protected from freezing (above 32°F) and is also inaccessible to children and animals.

Pesticide Disposal And Container Handling: Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. If empty: Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

{Alternate Storage and Disposal instructions for Bag-On-Valve packaging.}

STORAGE AND DISPOSAL

Store in a cool, dry (preferably locked) place that is away from heat or open flame, in an area that is protected from freezing (above 32°F and below 120°F) and is also inaccessible to children and animals.

Pesticide Disposal And Container Handling: Nonrefillable container. Do not reuse or refill this container. Contents under pressure. Do not puncture or incinerate.

If empty: Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

FIRST AID		
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. 	
going for treatme	t container or label with you when calling a poison control center or doctor, or ent. For additional information on this pesticide product (including health al emergencies or pesticide concerns), you may call 1-800-628-9653, at any time.	

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to aquatic organisms, including fish and aquatic invertebrates. To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treated area. Do not apply directly to or near water. Drift and run-off from treated areas may be hazardous to fish in water adjacent to treated areas. Do not contaminate water when disposing of equipment wash-water or rinsate. See Directions for Use for additional precautions and requirements.

MASTER LABEL

October 25, 2012

This pesticide is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product to allow it to drift to blooming crops if bees are visiting the treatment area.

PHYSICAL & CHEMICAL HAZARDS

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

{Alternate Physical & Chemical Hazards for Bag-On-Valve packaging.}

Combustible. Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

Distributed by:

W.F. Young, Inc. 302 Benton Drive E. Longmeadow, MA 01028 ©WFY RM# Made in U.S.A.

www.absorbine.com

EPA Est. No. EPA Reg. No. 1543-15

{Additional Alternate Bullet Points}

[[Also] contains multiple sunscreens and coat conditioners including Aloe and Lanolin]

[[and is] pleasantly scented with Citronella]

[Blanket your horse with WFY0301 protection from Absorbine®]

[Broad-spectrum control from Absorbine®]

[Protect your horses and dogs with Absorbine®]

[Performance is not affected by water, sweat, sun, dust or dirt]

[Also for use on dogs and puppies (over 12 weeks of age)]

[Kills ticks on dogs and puppies (over 12 weeks of age)]

[Bug Block® Technology extends repellency]

[Stops bugs before they bite]

October 25, 2012

[Blocks bugs from biting]
[24 hours a day 7 days a week for up to 17 days]
[24/17 pest protection]
[24/7 pest protection]
[Round-the-clock [premium pasture] protection]
[Works day and night]
[For use on horses, ponies (over 12 weeks of age), dogs and puppies (over 12 weeks of age)]
[Quick knockdown [kill and repellency protects for up to 17 days]]
[Continuous Spray – No Pumping Required]
[Quick & Even Coverage]
[Any Angle Spray]
[Continuous Silent Spray]
[Whisper [Quiet] Spray Mist]
[[with] Easy Swipe® [applicator]]

[] Denote alternate text in addition to any subset of the directions for use

MASTER LABEL

October 25, 2012

{SUB-LABEL FOR ROLL-ON PACKAGING}

WFY0301

[Weatherproof Insecticide & Repellent]

[The Horse World's Most Trusted Name® [Since 1892]]

[Field tested and proven effective]

[Kills and repels [biting and nuisance flies, gnats, mosquitoes on horses] [for up to 17 days]]

[Kills and repels biting and nuisance flies, ticks that may carry Lyme Disease and mosquitoes including the Culex species which has been known to transmit West Nile Virus]

[Long-lasting repellency that protects and stays active for up to 17 days]

[Weatherproof formula [binds to the hair shaft to repel and protect from bugs, sun, sweat, water, dust and dirt] [for up to 17 days]]

[[Sun] [Sweat] [water and rain] resistant formula [that produces a shine that shields]] [Stays active for up to 17 days]

[17-day [waterproof] [pasture] protection]

[Extends repellence for 17 days [with Bug Block® Technology]]

[Bug Graphics: fly, mosquito, tick, gnat]

[Weather Graphics]

[Kills [& Repels] more than 70 species]

[[With] UltraBond Technology]

{Additional alternate bullet points listed at end of label}

ACTIVE INGREDIENTS:

Permethrin*	0.50%
Pyrethrins	0.10%
Piperonyl Butoxide**	1.00%
OTHER INGREDIENTS:	. 98.40%
TOTAL:	100.00%

^{*}cis/trans ratio: Min. 35% (+/-) cis and Max. 65% (+/-) trans.

KEEP OUT OF REACH OF CHILDREN CAUTION

See Back/Side Label Panel for Additional Precautionary Statements

BT-4	C	
Ver	Contents	

^{**(}butylcarbityl)(6-propylpiperonyl) ether and related compounds

MASTER LABEL

October 25, 2012

READ ENTIRE LABEL BEFORE EACH USE ON ANIMAL USE - USE ONLY ON HORSES AND PONIES AND FOALS (Over 12 Weeks of Age)

DIRECTIONS FOR USE

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

USE RESTRICTIONS

• Do not store near or use with oxidizing agents. • This product is not for use on foals less than 12 weeks of age. • This product is not for use on horses intended for human consumption.

HOLD CONTAINER UPRIGHT. SHAKE WELL BEFORE USING.

Ready to use. No mixing necessary.

17-day weatherproof formula provides long-lasting repellency and protection from biting and nuisance flies, gnats, ticks and mosquitoes. This unique formula also contains multiple sunscreens and coat conditioners including Aloe and Lanolin and it is pleasantly scented with Citronella.

HORSES AND PONIES (Over 12 Weeks of Age):

Kills and repels biting and nuisance flies, gnats, mosquitoes and ticks for up to 17 days. Including Horse Flies, Stable Flies, Face Flies, Horn Flies, Deer Flies, House Flies, Black Flies, Cluster Flies, Sciarid Flies, Gnats, Midges, Punkies, No-See-Ums, Deer Ticks, Lone Star Ticks, Chiggers, American Dog Ticks, Brown Dog Ticks, Gulf Coast Ticks, Fleas and Lice.

Do not wet skin or apply to the point of dripping or exceed two ounces per application. Reapply each time animal is washed or exposed to heavy rain for best results. After application, brush thoroughly to bring out bright sheen on the coat.

Remove cap from bottle. Apply around **horse's and pony's** nose, eyes, ears and mouth. May also be used as a spot treatment on areas where flies gather. Avoid direct application to eyes, nose and mouth. Replace cap after use. For initial treatment, apply daily for 2 to 3 days.

MASTER LABEL

October 25, 2012

STORAGE AND DISPOSAL

Pesticide Storage: Store in a cool, dry (preferably locked) place that is away from heat or open flame, in an area that is protected from freezing (above 32°F) and is also inaccessible to children and animals.

Pesticide Disposal And Container Handling: Non-refillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

	FIRST AID
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.
going for treatme	container or label with you when calling a poison control center or doctor, or ent. For additional information on this pesticide product (including health all emergencies or pesticide concerns), you may call 1-800-628-9653, at any time.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove contaminated clothing and wash clothing before reuse.

PHYSICAL & CHEMICAL HAZARDS

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

Distributed by:

W.F. Young, Inc.
302 Benton Drive
E. Longmeadow, MA 01028
©WFY
RM#
Made in U.S.A.
www.absorbine.com

EPA Est. No. EPA Reg. No. 1543-15

MASTER LABEL

October 25, 2012

{Additional Alternate Bullet Points}

[[Also] contains multiple sunscreens and coat conditioners including Aloe and Lanolin]

[[and is] pleasantly scented with Citronella]

[Blanket your horse with WFY0301 protection from Absorbine®]

[Broad-spectrum control from Absorbine®]

[Protect your horses with Absorbine®]

[Performance is not affected by water, sweat, sun, dust or dirt]

[Bug Block® Technology extends repellency]

[Stops bugs before they bite]

[Blocks bugs from biting]

[24 hours a day 7 days a week for up to 17 days]

[24/17 pest protection]

[24/7 pest protection]

[Round-the-clock [premium pasture] protection]

[Works day and night]

[For use on horses and ponies (over 12 weeks of age)]

[Quick knockdown [kill and repellency protects for up to 17 days]]

[Quick & Even Coverage]

[[with] Easy Swipe® [applicator]]

[] Denote alternate text in addition to any subset of the directions for use