

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

December 13, 2017

Randall Tosh SmartVet USA, Inc. 22201 W. Innovation Drive Olathe, KS 66061-1304

Subject: PRIA Label Amendment – R350 to reduce the withdrawal interval from 90 to 42 days; other minor label revisions Product Name: AiM-A EPA Registration Number: 88050-3 Application Date: April 28, 2017 Decision Number: 529085

Dear Mr. Tosh:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act 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 FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list 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 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 the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, please contact Gene Benbow by phone at 703-347-0235, or via email at <u>Benbow.Gene@epa.gov</u>.

Sincerely,

See the

Gene Benbow, Product Manager 7 Invertebrate & Vertebrate Branch 3 Registration Division (7505P) Office of Pesticide Programs

Note to Reviewer: [Brackets (and parenthesis) indicate alternate language]

АіМ-Атм

[Alternate Brand Names: Aim ATM Capsules; AIM-ATM; AiM A ABAMECTIN; AiM ABAMECTIN A]

Abamectin Insecticide Capsules For Control of Horn Flies on Beef Cattle and Non-Lactating Dairy Cows

Active Ingredients Abamectin	Percent By Weight
(Avermectin B1a and Avermectin B1b)	
Total	100.00%

EPA Reg. No. 88050-NEW EPA Est. No. [88421-ITA-001][88050-ITA-1][88050-AR-001][88050-OK-1][XXXXX-XX-XXX]

KEEP OUT OF REACH OF CHILDREN

CAUTION

See [Back] [Side][Bottom] Panel(s) for First Aid and Additional Precautionary Statements

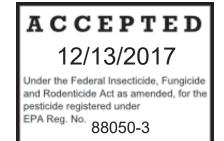
NET CONTENTS:

[30 x AiM-A capsules of 0.338 fl oz (10ml) each (total 10.14 fl oz or 300 ml)] [[Thirty] [30 x] 0.338 fl oz (10 ml) capsules]

[150 x AiM-A capsules of 0.338 fl oz (10 ml) each (total 1.58 Qt or 1.5 L)] [[One hundred fifty] [150 x] 0.338 fl oz (10 ml) capsules]

[XX x AiM-A capsules of 0.338 fl oz (10 ml) each (total XX)] [XX x 0.338 fl oz (10 ml) capsules]

Distributed by: Agri Laboratories Ltd St. Joseph, Missouri, USA (800) 542 - 8916



PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if swallowed. Wash hands thoroughly with soap and warm water after handling and before eating, drinking, chewing gum, using tobacco, using the toilet. Do not smoke within 10 feet of capsules or while using Application Device to apply capsules. Wear waterproof gloves.

	FIRST AID			
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, and then continue rinsing eye. Call a poison control center or doctor for treatment advice. 			
If on skin or	• Take off contaminated clothing.			
clothing:	Rinse skin immediately with plenty of water for 15-20 minutes.Call a poison control center or doctor for treatment advice.			
If Inhaled:	• Move person to fresh air.			
II IIIIuicu.	 If person is not breathing call 911 or an ambulance then give artificial respiration, preferably mouth-to-mouth if possible. 			
	 Call a poison control center or doctor for treatment advice. 			
HOTLINE NUMBER: Have the product container or label with you when calling a poison				
control center or doctor, or going for treatment. For emergency medical treatment call				
1-800-255-3924. For customer service or to obtain product information, including the MSDS				
(or SDS), call 1-	(or SDS), call 1-800-542-8916 or 1-816-233-9533.			

Environmental Hazards: This pesticide is toxic to 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. Do not contaminate water when disposing of equipment washwaters. Apply this product only as specified on the label.

Physical or Chemical Hazards: Flammable. Keep away from heat and open flame.

The capsules are sensitive to heat and humidity. Do not expose to relative humidity below 30% or above 70% or temperatures below 50° F or above 80° F for extended period over 30 minutes as this may affect the level of capsule fragmentation.

User Safety Recommendations: If exposed to liquid users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change clothing.
- Do not smoke within 10 feet of capsules or while using Application Device to apply capsules.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This labeling must be in the possession of the user at the time of pesticide application.

Application Device:

- AiM-A is designed for use only with a compatible applicator device that carries the *SmartVet*TM *Approved VetCap Application Device* label (sold separately), and in accordance with its use directions and treatment method recommendations.
- Using any other application device or method could be unsafe, ineffective and/or cause harm or injury.
- Never leave the capsules in any Application Device for extended periods or forstorage.

Ambient Conditions - Storage; Transport & Usage:

- The softgel capsules are sensitive and can be damaged bycareless handling or use or storage outside of prescribed ranges of humidity and temperature.
- Performance may be compromised if not used according to label instructions.
- Do not store or transport capsules outside of 30-70% relative humidity or temperatures outside of 50-80° F.
- When ready to apply, do not expose capsules to humidity and temperature conditions outside of the specified ranges for periods greater than thirty(30) minutes or performance may be affected.
- Do not refrigerate or expose capsules to freezing conditions during storage as this may cause permanent damage.
- For best results, keep capsules in original sealed packaging until ready foruse.
- Do not use in rain or if rain is expected within 24 hours.

Application Restrictions:

- Do not use on cattle treated with an abamectin ear tag.
- Do not use on wet cattle or when rain is expected to wet cattle within 24 hours after treatment.
- Only apply when animal is between 15 feet and 30 feet distance from theuser.
- Do not smoke within 10 feet of capsules or while using Application Device to apply capsules.
- Do not apply treatment when bystanders are within 30 feet of the animal.
- Do not apply to any animals in or within 10 feet of bodies of water.
- Do not leave intact capsules in the field or attempt to re-use as this could jeopardize functioning of the Application Device. Dispose of these capsules per Pesticide Disposal section of this label.
- Do not allow farm dogs or other farm animals to come into contact with the pesticide or

residues.

How to Apply:

- Apply the capsules to the middle of the side of the animal's body anywhere between the front shoulders and 6 inches ahead of the base of the tail.
- Treating all animals on the same side (either all on the left or all on the right) assists with identification of those that have been treated.

Amount to Use; How Often; and Withdrawal Period:

• Apply AiM-A at the dosage shown on the following table. Care must be taken to apply the correct dosage.

Horn Flies		
Animal Weight	[Dose Size per Animal][Dosage (ml)]	
Greater than 600 lbs	1 capsule (10 ml)	

- AiM-A can be used on beef cattle and non-lactating dairy cows of all ages provided they are greater than 600 lbs.
- Do not treat any animal with this product if it has also been treated with another abamectin-containing product (e.g., the Y-Tex XP 820 Insecticide Cattle Ear Tags EPA Reg No. 39039-17)
- If a second application of AiM-A is necessary, do not make it within 42 days of the initial application.
- Do not use to treat cattle in feedlots.
- Do not use to treat cattle to be slaughtered within 42 days of treatment.

STORAGE AND DISPOSAL

Not for Use or Storage In or Around the Home

Do not contaminate water, food or feed by storage or disposal.

Pesticide Disposal:

Pesticide wastes are hazardous. Improper disposal of excess pesticide or rinsate is a violation of Federal law. If this product cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal:

Non-refillable container. Do not reuse or refill any parts of this container. Offer for recycling, if available. Dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Pesticide Storage:

Store in such a manner as to prevent cross contamination with other pesticides, fertilizers, food and feed. Store in original container and out of reach of children, preferably in a locked storage area. Store under conditions where relative humidity is kept between 30% and 70% and temperatures are maintained between 50° F and 80° F. Ensure the capsules are never refrigerated or exposed to freezing temperatures during storage, or for periods exceeding 30 minutes in

transport or use as this may permanently damage capsules.

[NOTE: The capsule coating is softgel and sensitive to ambient humidity. Do not expose to relative humidity below 30% or above 70% or temperatures below 50° F or above 80° F for extended period over 30 minutes or this may affect the level of capsule fragmentation. Remove the capsules from container only when ready to apply onto the animals and keep containers sealed at all other times. Handle the container and capsules in a manner as to prevent damage to the capsules. If the capsules or container are leaking or material spilled for any reason or cause, carefully dam up spilled material to prevent runoff. Refer to Precautionary Statements on label for hazards associated with the handling of this material. Do not walk through spilled material. Absorb spilled material with absorbing type compounds and dispose as directed for pesticides above.]

[NOTE: Handle the container and capsules in a manner as to prevent damage to the capsules. Store under conditions where relative humidity is kept between 30% and 70% and temperatures are maintained between 50° F and 80° F. Ensure the capsules are never exposed to freezing temperatures during storage, or for periods of greater than 30 minutes in transport or use. (See [side][back][bottom] panel for Directions for Use and Storage & Disposal).] [Read Directions for Use and Storage and Disposal carefully. Store in a cool, dry place. Remove Aim-A Capsules from container only when ready to apply. Do not expose to relative humidity below 30% or above 70% or temperatures below 50° F or above 80° F for extended period over 30 minutes or this may affect the level of capsule fragmentation.]

[IMPORTANT:

- The softgel capsules are sensitive and can be damaged by careless handling or use or storage outside of prescribed ranges of humidity and temperature.
- Performance may be compromised if not used according to label instructions.
- Do not store or transport capsules outside of 30-70% relative humidity or temperatures outside of 50-80° F.
- When ready to apply, do not expose capsules to humidity and temperature conditions outside of the specified ranges for periods greater than thirty(30) minutes or performance may be affected.
- Do not refrigerate or expose capsules to freezing conditions during storage as this may cause permanent damage.
- For best results, keep capsules in original sealed packaging until ready foruse.]

Conditions of Sale: The directions on this label are believed to be adequate and must be followed carefully. This product has been tested under different environmental conditions similar to those that are ordinary and customary for use of the product. However, it is impossible to eliminate all risks associated with the use of this product. Failure to follow label directions may cause injury to animals, humans and damage to the environment. Insufficient control of pests, injury or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of SmartVet USA, Inc. its agents, affiliates or assignees. To the extent

consistent with applicable law, all such risks shall be assumed by the user or buyer.

Limited Warranty and Limitation of Damages: SmartVet USA, Inc. warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, SmartVet USA, Inc. MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL, and no agent of SmartVet USA, Inc. is authorized to make or modify any warranties beyond those contained herein. Any damages arising from breach of this warranty shall be limited to direct damages and shall not include special, incidental or consequential damages resulting from the use or handling of this product.

[Manufactured by:] SmartVet USA, Inc. International Animal Health & Food Safety Institute 22201 W. Innovation Drive Olathe, Kansas 66061-1304

[Optional Marketing Text/Graphics and Brand/Company Logos:] [The Delivery System is covered by Patents US 8425932B2; US 2013/0216483A1 and United States Patent Application No 14/453930 (amongst others) [Designed by SmartVet] [Developed by SmartVet][Distributed by AgriLabs] [150 Capsules] [150 Capsule Bulkpack] [(10 foil bags x 15 AiM-A Capsules)] [2 foil bags x 15 AiM-A Capsules)] [X foil bags x X AiM-A Capsules][To open, cut along dotted line with a sharp knife] [Tear here to open] [Fragile.] [Handle with care.] [This side up.] [Designed Exclusively for Use with VetGun (sold separately)] [Work Smarter, Not Harder] [An Innovative Insecticide Delivery System] [Precision Insecticide Delivery System] [SmartVet] [Work Smarter, Not Harder] [Agri Labs] [VetGun+AIM-A=(dead fly image)] [VetGun+AIM=(dead fly image)]



[VetGun[™]][Applicator]

[Labeling on foil bag containing capsules:]

AiM-A

Active Ingredient: 3.15% Abamectin (Avermectin B1a and Avermectin B1b)

Keep Out of Reach of Children

Caution

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

Not For Individual Resale

Net Contents: 15 x 0.338 fl.oz. (10 ml) capsules

- Apply only with a SmartVet Approved VetCap Application Device and inaccordance with its use directions and treatment method recommendations.
- Do not allow farm dogs or other farm animals to come into contact with the pesticide or residues.
- For best results transport the capsules in original sealed packaging until loading into Application Device.

BATCH:

Distributed by: Agri Laboratories Ltd, St. Joseph, Missouri, USA (800) 542-8916 EPA Reg. No. 88050-NEW

[Labeling on each capsule:]	AiM-A
	EPA Reg. No. 88050-NEW
	Caution
	3.15% Abamectin