



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

9 July 2014

VIA EMAIL

Mr. Terry McNamara, Agent
SmartVet USA, Inc.
International Animal Health & Food Safety Institute
c/o Exponent
1150 Connecticut Avenue, NW, Suite 1100
Washington, DC 20036

Subject: Label Amendment – Clarifying Treatments to Lice, Revising Pesticide Storage Text,
Adding Marketing Claims, and Other Revisions

Product Name: AIM-L
EPA Registration Number: 88050-2
Submission Date: June 23, 2014
Decision Number: 492546

Dear Mr. McNamara:

The label amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended is **acceptable**.

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.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) 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

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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. If you have any questions regarding this action, please contact Michael Walsh by phone at (703) 308-2972 or via email at "walsh.michael@epa.gov".

Sincerely,

A handwritten signature in black ink that reads "Mark ES". The "M" is large and stylized, followed by "ark" in a smaller, cursive script. To the right, the initials "ES" are written in a large, bold, cursive font.

Mark Suarez, Product Manager 13
Insecticide Branch
Office of Pesticide Programs

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

AIM-L

[Alternate Brand Name: Aim L™ Capsules]

Lambda Cyhalothrin with Piperonyl Butoxide Insecticide Capsules For Control of Horn Flies and Face Flies[, Biting Lice and Sucking Lice] on Beef Cattle

	<u>Percent By Weight</u>
Active Ingredients	
Lambda Cyhalothrin.....	1.50%
Piperonyl Butoxide*.....	7.50%
Other Ingredients	<u>91.00%</u>
Total	100.00%

*(butyl carbityl) (6-propylpiperonyl) ether and related compounds

EPA Reg. No. 88050-2
EPA Est. No. [88421-ITA-001][88050-AR-001][XXXXX-XX-XXX]

KEEP OUT OF REACH OF CHILDREN

CAUTION

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

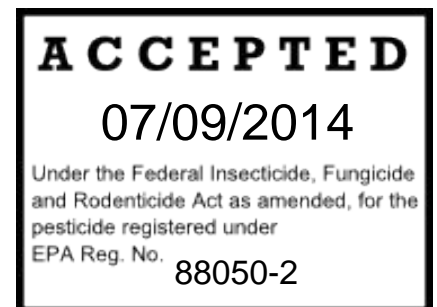
NET CONTENTS:

[30 x AIM-L 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-L 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-L 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.

	FIRST AID
If Swallowed:	<ul style="list-style-type: none">• 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 to an unconscious person.
If in Eyes:	<ul style="list-style-type: none">• 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 clothing:	<ul style="list-style-type: none">• 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.
If Inhaled:	<ul style="list-style-type: none">• Move person to fresh air.• 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, call 1-800-542-8916 or 1-816-233-9533.	

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. Do not contaminate water when disposing of equipment washwaters. Apply this product only as specified on the label.

Physical or Chemical Hazards: The capsules are sensitive to heat and humidity. Do not expose to relative humidity above 50% or temperatures above 70F for extended periods, such as 1 – 3 hours, as this may affect the level of capsule fragmentation.

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

In the field do not remove the capsules from container until ready to apply. For best results transport the capsules in original sealed packaging until loading into Application Device.

Apply only with a SmartVet™ Approved Vetcap Application Device (sold separately), and in accordance with its use directions and treatment method recommendations

Never leave the capsules in any Application Device – return all unused capsules to original container and store as directed.

Only apply when animal is between 15 feet and 30 feet distance from the user.

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.

Do not allow farm dogs or other farm animals to come into contact with the pesticide or residues.

AIM-L is designed for use only with a compatible applicator device that carries the ‘*SmartVet™ Approved VetCap Application Device*’ label. Using any other application device or method could be unsafe, ineffective and/or cause harm or injury.

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.

Amount to Use: Apply AIM-L at the dosages shown on the following table. Care must be taken to apply the correct dosage.

Horn Flies and Face Flies[, [Biting Lice] and [Sucking] Lice]	
Animal Weight	[Dose Size per Animal][Dosage (ml)]
Greater than 600 lbs	1 capsule (10 ml)

AIM-L can be used on beef cattle of all ages provided they are greater than 600 lbs. Treatment for flies [or lice] can be repeated as needed but not more often than once every 2 weeks and do not apply more often than four times within any 6-month period. [For optimal lice control, an initial application followed by a second treatment 2 weeks later is recommended.]

AIM-L does not control cattle grubs.

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 these wastes 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. Puncture and 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 50% and temperatures are maintained between 50F and 70F. Ensure the capsules are never exposed to freezing temperatures during storage, transport or use [-this may permanently damage capsules]. If inadvertently exposed to high heat and humidity, the capsules can normally be restored to ideal conditions by placing them for 24 to 72 hours in cool & dry conditions where relative humidity is between 30% and 50% and temperatures do not exceed 70F.]

[NOTE: The capsule coating is softgel and sensitive to ambient humidity. Do not expose to relative humidity above 50% or temperatures above 70F for any extended period, such as over 1 hour, 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 50% and temperatures are maintained between 50F and 70F. Ensure the capsules are never exposed to freezing temperatures during storage, 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-L Capsules from container only when ready to apply. Do not expose to relative humidity above 50% or temperatures above 70F for [any] extended period, [such as over 1 hour,] or this may affect the level of capsule fragmentation.]

[IMPORTANT:

- The soft gel capsule coating is sensitive and can be damaged by certain ambient conditions and rough handling.
- Do not expose capsules to relative humidity above 50% or temperatures above 70F for any extended period over 1 hour, or this may affect level of capsule fragmentation - restoring may be possible in some cases, refer 'Pesticide Storage' section of label.
- Do not refrigerate or expose to freezing conditions, this may permanently damage capsules.
- Remove the capsules from container only when ready to apply onto the animals and keep containers sealed at all other times.]

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, 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 warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, SmartVet USA 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 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.

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:]

[Designed by SmartVet]

[Developed by SmartVet][Distributed by AgriLabs]

[150 Capsules]

[150 Capsule Bulkpack]

[(10 Tubes x 15 Aim-L Capsules)]

[5 x [(5 Tubes x 6 Aim-L Capsules)]]

[To open, cut along dotted line with a sharp knife]

[Fragile.]

[Handle with care.]

[This side up.]
[Designed Exclusively for Use with VetGun (sold separately)]
[Work Smarter, Not Harder]
[An Innovative Insecticide Delivery System]
[SmartVet] [Work Smarter, Not Harder]
[Agri Labs]
[VetGun+AIM-L=(dead fly image)]



developed by:



distributed by:



[VetGun™][Applicator]

[Labeling on transparent sleeve containing capsules:] [Not For Individual Resale]
[Labeling on Styrofoam carton containing sleeves of capsules:] [Not For Individual Resale]

[Labeling on each capsule:]
AIM-L
EPA Reg. No. 88050 -2
Caution
1.50% Lambda Cyhalothrin
7.50% Piperonyl Butoxide