

88050-2

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

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Mr. Terry McNamara  
SmartVet USA, Inc.  
International Animal Health & Food Safety Institute  
22201 W. Innovation Drive  
Olathe, KS 66061-1304

NOV - 7 2013

Dear Mr. McNamara:

Subject: Application for Pesticide Notification (PRN 98-10)  
Change Net Contents on label and revise use table accordingly  
AIM-L  
EPA Reg. No. 88050-2  
Your submission dated October 17, 2013

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated October 17, 2013 for the above product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds the action requested falls within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on nonrefillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions regarding this letter, please contact Dana Pilitt, Ph.D. at (703) 305-7071 or via e-mail at [pilitt.dana@epa.gov](mailto:pilitt.dana@epa.gov).

Sincerely,

A handwritten signature in cursive script that reads "Richard Gebken".

Richard Gebken  
Product Manager 13  
Insecticide Branch  
Registration Division (7505P)

88050-2 D 484297

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

<b>EPA</b> United States <b>Environmental Protection Agency</b> Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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**Application for Pesticide - Section I**

1. Company/Product Number 88050-2	2. EPA Product Manager Mark Suarez	3. Proposed Classification  <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) SmartVet USA, Inc./AIM-L	5. PM 13	
5. Name and Address of Applicant (Include ZIP Code)  SmartVet USA, Inc. International Animal Health & Food Safety Institute 22201 W. Innovation Drive Olathe, Kansas 66061-1304  <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:  <div style="text-align: center;"><b>NOTIFICATION</b></div> EPA Reg. No. _____ Product Name <u>NOV - 7 2013</u>

**Section II**

<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated XX-XX-XX <input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated XX-XX-XX <input type="checkbox"/> "Me Too" Application <input type="checkbox"/> Other - Explain below.
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Explanation: Use additional page(s) if necessary. (For section I and Section II.) Notification per PR Notice 98-10. This notification 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 confidential statement of formula of this product. I understand that it is a violation of 18 USC 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 1 of FIFRA. Please see cover letter for details.

**Section III**

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No  If "Yes" Unit Packaging wgt. 0.338 fl oz (10 ml)	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No  If "Yes" Package wgt.	No. per Container 30 or 150	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) Plastic Bag	
*Certification must be submitted		3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 30 or 150 10-ml capsules	
5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product			6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		

**Section IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Terry McNamara	Title Authorized Representative, SmartVet USA, Inc.	Telephone No. (Include Area Code) 913-428-6229

**Certification**

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received <b>(Stamped)</b>
2. Signature  BY: <i>Terry McNamara</i>	3. Title Authorized Representative, SmartVet USA, Inc.	
4. Typed Name: Terry McNamara	5. Date: 10/17/2013	

1150 Connecticut Ave. NW  
Suite 1100  
Washington, DC 20036  
telephone 202-772-4900  
facsimile 202-772-4979  
www.exponent.com

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Exponent®

October 17, 2013

Mark Suarez  
Product Manager 13  
Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Dr.  
Arlington, VA 22202

**SUBJECT: Application for Pesticide Notification (Revised Label)  
AIM-L, EPA Registration Number 88050-2**

Dear Mr. Suarez:

On behalf of our client, SmartVet USA, Inc. (SmartVet, EPA Company Number 88050, International Animal Health & Food Safety Institute, 22201 W. Innovation Drive, Olathe, Kansas 66061-1304), Exponent is submitting an Application for Pesticide Notification.

In explanation, SmartVet is adding a new package size containing 150 capsules in addition to the current package size containing 30 capsules. With this notification we are changing net contents on the label. The Directions for Use included a table specifying that one container of 30 capsules would treat 30 animals. This is no longer appropriate for a package containing 150 capsules, so this entry in the table has been deleted. Please note that the Directions for Use already approved by EPA have not changed. All changes are highlighted on one copy of the label.

In support of this action, the following documents are being submitted:

- Application for Pesticide Notification per PR Notice 98-10 (form 8570-1);
- Product Label v2.0 (one copy with changes highlighted, and one copy unmarked); and
- Agency's letter and stamped label dated 4/25/2013 (for Agency's reference).

If you have any questions, please contact me at 913-428-6229 or [tmcnamara@exponent.com](mailto:tmcnamara@exponent.com).

Sincerely,



Terry McNamara  
Authorized Representative for  
SmartVet USA, Inc.

Enclosure

cc: Randall Tosh, SmartVet USA, Inc.

**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,  
Face Flies, Biting Lice and Sucking Lice on Beef Cattle

	<u>Percent</u> <u>By Weight</u>
<b>Active Ingredient</b>	
Lambda Cyhalothrin.....	1.50%
Piperonyl Butoxide*.....	7.50%
<b>Other Ingredients</b> .....	<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][XXXXXX-XX-XXX]

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

See [Back] [Side] 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 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 0.338 fl oz (10 ml) capsules]

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

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

**NOTIFICATION**

**NOV - 7 2013**

**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.

	<b>FIRST AID</b>
If Swallowed:	<ul style="list-style-type: none"><li>• Call a poison control center or doctor immediately for treatment advice.</li><li>• Have a person sip a glass of water if able to swallow.</li><li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li><li>• Do not give anything to an unconscious person.</li></ul>
If in Eyes:	<ul style="list-style-type: none"><li>• 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.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
If on skin or clothing:	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
If Inhaled:	<ul style="list-style-type: none"><li>• Move person to fresh air.</li><li>• If person is not breathing call 911 or an ambulance then give artificial respiration, preferably mouth-to-mouth if possible.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>HOTLINE NUMBER:</b> 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.

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## 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 and in a cooler up 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 above.

Only apply when animal is between 15 feet and 30 feet distant 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, Face Flies, [Biting Lice] and [Sucking] Lice	
Animal Weight	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 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 under conditions where relative humidity is kept between 30% and 50% and temperatures are maintained between 40F and 70F. If required, store in a cooler or refrigerator that is used exclusively for animal health products. Ensure the capsules are never exposed to freezing temperatures during storage, transport or use. 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 20% and 50% and temperatures do not exceed 70F. 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.

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 1 – 3 hours, 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.

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**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.

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



[Labeling on each capsule:]

AIM-L  
EPA Reg. No. 88050 -2  
Caution  
1.50% Lambda Cyhalothrin  
7.50% Piperonyl Butoxide