



United States  
**Environmental Protection Agency**  
Washington, DC 20460

<input checked="" type="checkbox"/>	<b>Registration</b>
<input type="checkbox"/>	<b>Amendment</b>
<input type="checkbox"/>	<b>Other</b>

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/Product Number 70585-	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Novartis Animal Health US, Inc. / NAH 2	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Novartis Animal Health US, Inc. c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. NW Gig Harbor, WA 98332 <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: EPA Reg. No. [REDACTED] Product Name [REDACTED]	

**Section - II**

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

This application is a repack of a pending registration and is considered a secondary application to the [REDACTED] primary application. Although no data are being submitted with this application, because it is tied to a pending application classified under R310 and it was submitted over two weeks from the primary submission, Novartis requests that this application be processed under R310. The PRIA fee for this category is \$4,578 and the review timeframe is 6 months. Should you have any questions, please contact me at (email) Ross@PyxisRC.com or (phone) 253-853-7369.

**Section - III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. 0.67, 1.34, 2.68, 4.02 ml.	No. per container 3	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2.01, 4.02, 8.04, 12.06 ml.		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 Paper glued Stenciled			<input type="checkbox"/> Other _____		

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Ross Gilbert	Title Agent	Telephone No. (Include Area Code) 253-853-7369
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 (Stamped)
2. Signature 	3. Title Agent	
4. Typed Name Ross Gilbert	5. Date 7/8/10	



United States  
**Environmental Protection Agency**  
 Washington, DC 20460  
**Formulator's Exemption Statement**  
 (40 CFR 152.85)

Applicant's Name and Address Novartis Animal Health US, Inc. 3200 Northline Avenue, Suite 300 Greensboro NC, 27408	EPA File Symbol/Registration Number 70585-
	Product Name NAH 2
	Date of Confidential Statement of Formula (EPA Form 8570-4) 07/08/2010

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Fipronil

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

(A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

(B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Fipronil		
*Product ingredient source information may be entitled to confidential treatment*		
Signature 	Name and Title Ross Gilbert/ Agent	Date 7/8/10



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
**WASHINGTON, D.C. 20460**

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**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Novartis Animal Health US, Inc., c/o Pys's Regulatory Consulting, 4110 136th St. NW, Gig Harbor, WA 98332, 253-853-7369	EPA Registration Number/File Symbol 70585-RE
Active Ingredient(s) and/or representative test compound(s) Fipronil	Date 8/9/2010
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor nonfood use	Product Name NAH 2

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it 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.

Signature

Date

8/9/10


Typed or Printed Name and Title

Ross Gilbert / Agent

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**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

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**DATA MATRIX**


Date		EPA Reg. No./File Symbol		Page / of		
July 22, 2010		70585-RE		9 / 9		
Applicant's/Registrant's Name & Address						
Novartis Animal Health US, Inc. 3200 Northline Avenue, Suite 300 Greensboro NC 27408						
Product						
NAH 1						
Ingredient	Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>Product Specific Data Requirements</b>						
830.1550		Product Identity and Composition	48059501	Sergeants Pet Care Products, Inc.	PAY	
830.1600		Description of Materials Used to Produce the Product	48059501	Sergeants Pet Care Products, Inc.	PAY	
830.1620		Description of Production Process				Not required
830.1650		Description of Formulation Process	48059501	Sergeants Pet Care Products, Inc.	PAY	
830.1670		Discussion of Formation of Impurities	48059501	Sergeants Pet Care Products, Inc.	PAY	
830.1700		Preliminary Analysis				Not required
830.1750		Certified Limits	48059501	Sergeants Pet Care Products, Inc.	PAY	
830.1800		Enforcement Analytical Method				Not required
830.6302		Color	48059502	Sergeants Pet Care Products, Inc.	PAY	
830.6303		Physical State	48059502	Sergeants Pet Care Products, Inc.	PAY	
Signature			Name and Title		Date	
			Ross Gilbert, Consultant		7/22/10	

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**DATA MATRIX**


Date July 22, 2010		EPA Reg. No./File Symbol 70585-		Page 2 of 3		
Applicant's/Registrant's Name & Address		Product				
Novartis Animal Health US, Inc. 3200 Northline Avenue, Suite 300 Greensboro NC 27408		NAH 1				
Ingredient	Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6304		Odor	48059502	Sergeants Pet Care Products, Inc.	PAY	
830.6313		Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	48059502	Sergeants Pet Care Products, Inc.	PAY	
830.6314		Oxidation/Reduction: Chemical Incompatibility	48059502	Sergeants Pet Care Products, Inc.	PAY	
830.6315		Flammability	48059502	Sergeants Pet Care Products, Inc.	PAY	
830.6316		Explosibility	48059502	Sergeants Pet Care Products, Inc.	PAY	
830.6317		Storage Stability	48059502	Sergeants Pet Care Products, Inc.	PAY	
830.6319		Miscibility	48059502	Sergeants Pet Care Products, Inc.	PAY	
830.6320		Corrosion Characteristics	48059502	Sergeants Pet Care Products, Inc.	PAY	
830.6321		Dielectric Breakdown Voltage				
Signature			Name and Title		Not required	
			Ross Gilbert, Consultant		Date 7/22/10	

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**DATA MATRIX**

Date July 22, 2010		EPA Reg. No./File Symbol 70585-	Page 3 of 9		
Applicant's/Registrant's Name & Address		Product			
Novartis Animal Health US, Inc. 3200 Northline Avenue, Suite 300 Greensboro NC 27408		NAH 1			
Ingredient	Fipronil (CAS No. 120068-37-3)	MRID Number	Submitter	Status	Note
Guideline Reference Number	Guideline Study Name	48059502	Sergeants Pet Care Products, Inc.	PAY	
830.7000	pH				
830.7050	UV/Visible Absorption				Not required
830.7100	Viscosity	48059502	Sergeants Pet Care Products, Inc.	PAY	
830.7200	Melting Point/Melting Range				Not required
830.7220	Boiling Point/Boiling Range				Not required
830.7300	Density/Relative Density/Bulk Density	48059502	Sergeants Pet Care Products, Inc.	PAY	
830.7370	Dissociation Constants in Water				Not required
830.7520	Particle size, fiber length, diameter distribution				Not required
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method				Not required
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				Not required
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				Not required
830.7840	Water Solubility: Column Elution Method; Shake Flask Method				Not required
Signature		Name and Title	Ross Gilbert, Consultant		Date
					7/22/10

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Date	July 22, 2010	EPA Reg. No./File Symbol	70585-	Page 4 of 4
Applicant's/Registrant's Name & Address		Product		
Novartis Animal Health US, Inc. 3200 Northline Avenue, Suite 300 Greensboro NC 27408		NAH 1		
Ingredient Fipronil (CAS No. 120068-37-3)				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status
830.7860	Water Solubility, Generator Column Method			
830.7950	Vapor Pressure			
Signature	<i>mg</i>	Name and Title		Date
		Ross Gilbert, Consultant		7/22/10
				Note
				Not required
				Not required