

US EPA ARCHIVE DOCUMENT



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

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

July 30, 2008

MEMORANDUM

Subject: Name of Pesticide Product: FREEDOM 50 PLUS IGR SPOT ON FOR DOGS
EPA Reg. No. /File Symbol: 75844-I
DP Barcode: D354842
Decision No.: 389796
Action Code: R301
PC Codes: 109701 (Permethrin: 50.0%)
129032 (Pyriproxyfen: 1.2%)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
7-30-2008
M. Hashmi

To: Linda DeLuise/George LaRocca, RM 13
Insecticide Branch
Registration Division (7505P)

Registrant: ANDREW M MARTIN CO. NV. INC.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
109701 Permethrin	50.0%
129032 Pyriproxyfen	1.2%
<u>Other Ingredient(s):</u>	<u>48.8%</u>
	100.0%

ACTION REQUESTED: The Risk Manager requests:

“This is in response to our meeting and your review of 5/12/2008.”

BACKGROUND: The material available for review includes a proposed label (product name: Freedom 50 Plus IGR Spot On For Dogs) with the following dosages: for dogs weighing 33 lbs or less: 1.35 cc applied to the skin of the dog's back between the shoulder blades; for dogs weighing 33-66 lbs: 1.35 cc applied to the skin of the dog's back between the shoulder blades and 1.35 cc to the skin directly in front of the base of the dog's tail; for dogs weighing more than 66 lbs: 2.7 cc applied to the skin of the dog's back between the shoulder blades and 2.7 cc to the skin directly in front of the base of the dog's tail. The label includes the statement: "DO NOT USE ON CATS." The material received also includes CSF, a data matrix, and a 3-page document titled: "Further information to support the registration Freedom 50 Plus IGR Spot-On for Dogs [75844-I]. Response to May 15 DER signed by Byron Backus.

COMMENTS AND RECOMMENDATIONS:

1. The revised dosages are acceptable, as they are consistent (at least for the Permethrin component) with the dosages for EPA Reg. No. 773-73, which has a label declaration of 65% permethrin. With these revised dosages, the studies in MRIDs 40806701 and 41056906 can be used to satisfy the companion animal safety data requirements.
2. The acute toxicity data can be bridged, in part, from the studies used to support the registration of EPA Reg. No. 773-73. These studies (MRIDs 41056901 through 41056905) were previously reviewed (memorandum dated 5/25/89) by William S. Woodrow of the Precautionary Review Section (copy attached). The registrant should revise the data matrix to cite these studies, and to complete the bridging process should also cite the studies (MRIDs 46011901 through 46011905) previously used to support the registration of EPA Reg. No. 75844-7 (refer to the memorandum of 1/29/2008 from Masih Hashim to Olga Odiott). Alternatively, the registrant can use the cite-all method of support.
3. The companion animal safety study data for Pyriproxyfen (Nylar) dogs can be satisfied by citing the 52-week (dog) feeding study in MRID 42178309.
4. With the citations indicated above, the acute toxicity and companion animal study data requirements would be satisfied for the registration of this product.
5. The marketing of this product in 240 and 480 cc bottles for use in kennels, shelters, boarding and grooming establishments is acceptable.
6. TRB notes that, from p. viii of the Permethrin Reregistration Eligibility Decision (revision dated December 2007): "The Agency is requiring a companion animal study (870.7200) for petrmethrin products used on domestic animals. The study is to ensure that pesticide formulations for the treatment of external pests on domestic animals have an adequate margin of safety for the treated companion animal. In addition, data from companion animal safety studies also serve as a basis for product labelling. This data requirement will be included on the PDCI." This data call-in may be required for this product at some future date if it is determined that the cited companion animal studies are inadequate.
7. The CSF (copies dated 01/19/2008 and 02/06/2008) for the proposed product should also be reviewed and accepted by the TRB Chemistry Team.