EFFICACY REVIEW

PRODUCT: Y-TEX BOVAMECT™ Cattle Ear Tags

FILE SYMBOL: 39039-RT

DATE: 1/21/09

GLP: N/A

BARCODE: D360876

DECISION: 380725

CHEMICAL: Abamectin (8%)

CHEMICAL NUMBER: 122804

PURPOSE: Review rebuttal to Agency efficacy review dated December 11, 2008 (D359458).

MRIDS: N/A

TEAM REVIEWER: Tom Harris

EFFICACY REVIEWER: Kable Bo Davis, M.S., Entomologist

BACKGROUND:
In an Agency efficacy review dated December 11, 2008 (D359458), the following recommendations were recorded:

1. The submitted data support control claims for the following pests: horn flies (3 months; 1 tag per animal), horn flies (4 months; 2 tags per animal) and Gulf Coast ticks. In addition, the submitted data supports “aids in the control” claims for the following pests: American dog ticks, lone star ticks and cattle fever ticks.

2. The submitted data do not support the addition of “aids in the control” claims for face flies. All references to face flies must be deleted from the label. To have this claim added back on in the future, additional data must be submitted showing that EPA File Symbol 39039-RT is efficacious against face flies. The percent control of horn flies infesting cattle treated with product must be at least ~75%.

3. The provided argument used to support the addition of spinose ear ticks to the pending label is not adequate. Acceptable data must be submitted. The Agency acknowledges that it may be difficult to find cattle naturally infested with spinose ticks. However, and alternate acceptable method would be to artificially infest cattle with laboratory populations. These data may be submitted as a condition of registration.

4. Throughout the label, revise the phrase “other tick species” to read “other listed tick species”.

5. The directions for use are unclear as to the residual activity of this product against ticks other than Gulf Coast ticks. The label must clearly state that the 4 month residual claim only applies to Gulf Coast ticks and not to the other listed ticks (American dog tick, lone star tick, cattle fever ticks).
A rebuttal to the above referenced review was submitted on January 12, 2009.

RECOMMENDATIONS:

1. The registrant wishes to add the statement "XP 820 Tags have been shown to aid in control of American Dog Ticks, Lone Star Ticks and...for two to three months." to the pending label.

Agency Response- Due to the efficacy of Lone Star Ticks being 67% approximately 80 days post treatment, the above referenced statement is not acceptable. The statement may be revised to read "XP 820 Tags have been shown to aid in control of American Dog Ticks, Lone Star Ticks and ...for two months." If Lone Star Ticks are deleted from the label, the statement "XP 820 Tags have been shown to aid in the control of American Dog Ticks and ...for up to three months." would be acceptable.

2. The registrant wishes to add the statement "XP 820 Tags have been shown to aid in control of...and cattle fever ticks (Boophilus species) for two to three months." to the pending label.

Agency Response- The rebuttal document claims that additional field studies are planned by the USDA and Australian entomologists during 2009. The statement "XP 820 Tags have been shown to aid in control of...and cattle fever ticks (Boophilus species) for two to three months." is acceptable under the condition that these data are submitted and deemed acceptable.

3. The registrant wishes to extend the residual control claim for horn flies from four months to five months.

Agency Response- A five month control claim for horn flies is acceptable.

NOTE TO REGISTRANT: It is strongly recommended that the DIRECTIONS FOR USE be divided up according to pest. This would make it easier to assign the appropriate residual claim to the correct pest.