



New or Changes to Product Labels-New Pests Evaluation Report for Category B, Subcategory 3.11Application

Application Number: 2015-4095
Application: B.3.11
Product: Advantage 55 Flea And Lice Adulticide For Dogs 8 Weeks And Older Weighing Between 11 And 25 kg
Registration Number: 25127
Active ingredients (a.i.): 9.1% imidacloprid
PMRA Document Number : 2607555

Background

Advantage 55 Flea And Lice Adulticide For Dogs 8 Weeks And Older Weighing Between 11 And 25 Kg (Reg. No. 25127) is a spot-on domestic class product containing 9.1% imidacloprid. This product is registered for use against adult fleas on dogs, and is packaged in single doses adjusted for dogs in the specific labelled weight range. The entire dose is applied to the skin of the dog evenly in six to eight spots on the top of the back from the shoulder to the base of the tail. The product provides 4 weeks of flea control, but may be re-applied after one week if necessary.

Purpose of Application

The purpose of this application is to add the claim “for the treatment of lice infestations on dogs” to the label of Advantage 55 Flea And Lice Adulticide For Dogs 8 Weeks And Older Weighing Between 11 And 25 Kg.

Chemistry Assessment

Not required.

Health Assessments

Not required.

Environmental Assessment

Not required.

Value Assessment

Four efficacy trials were submitted in support of the addition of lice to the Advantage 55 Flea And Lice Adulticide For Dogs 8 Weeks And Older Weighing Between 11 And 25 Kg label. These trials were conducted on dogs of various sizes that were infested with lice. The trials tested products which were formulated with either imidacloprid, imidacloprid and permethrin, or imidacloprid and moxidectin (an anti-helminthic drug). The tested application rates were equivalent to those which are currently registered for these products. The submitted studies demonstrated 99% to 100% control of lice until study termination at 35 or 36 days following the application of a single treatment to dogs naturally infested with *Trichodectes canis*.

The submitted information was sufficient to support the addition of the claim “for the treatment of lice infestations on dogs” to the label for Advantage 55 Flea And Lice Adulticide For Dogs 8 Weeks And Older Weighing Between 11 And 25 Kg (Reg. No. 25127).

Conclusion

The addition of the claim “for the treatment of lice infestations on dogs” to the label for Advantage 55 Flea And Lice Adulticide For Dogs 8 Weeks And Older Weighing Between 11 And 25 Kg (Reg. No. 25127) was supported.

References

- 2558596 2015, VALUE ASSESSMENT of Advantage, Advantage II, K9 Advantix, and K9 Advantix II for Lice Control on Dogs, DACO: 10.1, 10.2, 10.2.1, 10.2.2, 10.2.3, 10.2.3.1, 10.2.3.2(C), 10.3, 10.3.1, 10.3.2, 10.4, 10.5, 10.5.1, 10.5.3

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