



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

Application Number: 2015-4601
Application: B.3.11
Product: K9 Advantix II Medium Dog
Registration Number: 29778
Active ingredients (a.i.): 8.8% imidacloprid, 0.44% pyriproxyfen, and 44% permethrin
PMRA Document Number : 2607593

Background

K9 Advantix II Medium Dog (Reg. No. 29778) is a spot-on domestic class product containing 8.8% imidacloprid, 0.44% pyriproxyfen, and 44% permethrin. K9 Advantix II Medium Dog is registered for application on dogs to control ticks, adult and larval fleas, and flea eggs. The product 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 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 K9 Advantix II Medium Dog label.

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 K9 Advantix II Medium Dog 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*. While a trial with a product containing pyriproxyfen was not conducted, it is reasonable to assume that the performance of products containing pyriproxyfen (i.e., K9 Advantix II Medium Dog) will perform at least as well as the tested products.

The submitted information was sufficient to support the addition of the claim “for the treatment of lice infestations on dogs” to the label for K9 Advantix II Medium Dog (Reg. No. 29778).

Conclusion

The addition of the claim “for the treatment of lice infestations on dogs” to the label for K9 Advantix II Medium Dog (Reg. No. 29778) 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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