



Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2017-2439
Application: B.1.1: New Source by Same Registrant
Product: *Beauveria bassiana* Strain Ant-03
Registration Number: 31230
Active ingredients (a.i.): *Beauveria bassiana* strain ANT-03
PMRA Document Number : 2820954

Purpose of Application

The purpose of this application is to add a new manufacturing site for *Beauveria bassiana* Strain Ant-03.

Product Characterization and Analysis Assessment

Information and data were provided on the manufacturing and quality control of *Beauveria bassiana* strain ANT-03 (TGAI) at the new manufacturing site. The described manufacturing and quality control processes, and representative batch data were adequate to demonstrate that the TGAI manufactured at the new location is equivalent to the previously registered product. No additional information or data are required to complete the Product Characterization and Analysis database for *Beauveria bassiana* strain ANT-03.

Health, Environmental and Value Assessment

Health, environmental and value assessments were not required for this application.

Conclusion

The PMRA has reviewed the information provided in support of the new manufacturing site. Based on the results of this review, the new manufacturing site is acceptable.

References

2763199 2017, manufacturing methods and quality assurance, DACO: M2.8 CBI
2763200 2017, potency estimation and product guaranty, DACO: M2.9.2
2763201 2017, analysis for microbial contaminants, DACO: M2.10.2

ISSN: 1911-8082

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