Veterinary Medicines Directorate

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Post Authorisation Assessments

Scalibor Protectorband 1.0 g Medicated Collar for Large Sized Dogs

Vm 01708/5079

•	25 March 2024	Minor change in the manufacturing process. Change to in-process tests or limits.
•	11 September 2023	Minor changes: – to an approved test procedure, for a starting material, reagent or intermediate used in the manufacturing process of the active substance, or for an excipient.
•	21 July 2023	One-off alignment of the product information with version 9.0* of the QRD templates.
•	05 May 2023	Deletion of a test procedure for the finished product.
•	04 May 2023	Deletion of a non-significant specification parameter of an excipient.
•	30 December 2022	Minor change in the manufacturing process. Minor change in the manufacturing process.
•	16 March 2022	Minor changes to an approved test procedure of the finished product.
•	05 October 2020	Change in the specification limits of an excipient.
•	01 October 2020	Changes to the labelling and package leaflet.
•	14 August 2020	Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited.
•	22 April 2020	Updates to the SPC following a Repeat Use procedure.
•	16 January 2020	Change in the name and address of the manufacturer of the finished product. Change in the name of the manufacturer of the finished product.
•	16 January 2020	Minor changes to an approved test procedure of the finished product.
•	13 November 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS
•	07 March 2018	Change in the name of a manufacturer of the active substance. Change in the name of an ASMF holder.
•	05 January 2017	Changes to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH.
•	28 September 2016	Update to layout and branding style of Mock-ups.
•	06 September 2016	Change in the name of the supplier of a starting material used in the manufacture of the active substance. Addition of two manufacturers of an intermediate used in the manufacturing process of the active substance.
•	22 July 2015	Deletion of non-significant in-process tests applied during

		the manufacture of the finished product.
•	07 May 2015	Change in the name of the manufacturer of the active substance.
•	01 April 2015	Changes to section 4.6 of the SPC.
•	28 November 2014	Update to the DDPS.
•	20 November 2013	Repeat Use Comment.
•	21 August 2013	Deletion of a manufacturing site.
•	14 February 2013	Variation to update the Active Substance Master File.
•	13 November 2012	Variation to update the ERA, in preparation of submitting a future repeat use application.
•	18 July 2012	Variation to harmonise the specifications for a non-pharmacopoeial excipient.
•	15 June 2011	Variation to add an additional manufacturing site for secondary packaging.
•	04 May 2010	Variation to change the legal category from POM-V to NFA-VPS.
•	19 April 2010	Variation to make changes to the label text on the small immediate packaging units.
•	31 March 2010	Variation to increase the batch size from 100kg to 300kg
•	26 March 2010	Renewal UK as CMS.
•	09 June 2009	Add SGS Life Science Services, France, as an additional site for finished product testing.
•	05 December 2008	Increase the batch size from 50 kg to 100 kg.
•	03 March 2006	Amendment to dossier.
•	16 August 2005	Add a source of the active substance.
•	07 September 2004	Renewal procedure.
•	11 April 2004	Change TSE status.
•	18 February 2004	Change to sachet text layout.
•	09 May 2003	Addition of a site for packaging and release.