Veterinary Medicines Directorate

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Post Authorisation Assessments

Flubenvet 5% w/w Premix for Medicated Feeding Stuff

Vm 00879/4184

•	18 May 2024	Deletion of titanium dioxide as a component or components of the colouring system.
•	01 March 2024	Deletion of packaging site for the finished product.
•	October 2023	Deletion of a manufacturing site responsible for manufacturing, primary packaging, secondary packaging, labelling, QC & stability testing and QP batch release.
•	25 January 2023	Submission of an updated certificate of suitability.
•	20 October 2022	Approval of mock ups.
•	01 September 2022	Addition of a batch release site for the finished product. Addition of a batch release site for the finished product. Addition of a manufacturing site of the finished product.
•	01 September 2022	Change in qualitative or quantitative composition of the immediate packaging. Additional site for QC testing of the finished product. Additional sites for QC testing of the finished product. Additional site for QC and stability testing of the finished product. Deletion of a non-significant specification parameter of the finished product.
•	11 June 2021	Addition of a secondary packaging site of the finished product. Addition of a primary packaging site of the finished product.
•	01 October 2020	Change of Marketing Authorisation Holder from Eli Lilly and Company Limited, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL to Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	10 May 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	09 April 2015	Submission of an updated certificate of suitability.
•	21 March 2012	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer Change in specification of the finished product
•	07 March 2012	Change of distributor
•	26 April 2011	Addition of a re-test period of the active substance of 60 months and a storage condition of ‘Do not store above

		30˚C’
•	16 February 2011	Submission of updated Ph. Eur. Certificates of Suitability for an active substance from an already approved manufacturer
•	16 February 2010	Addition of a manufacturer of the active substance
•	30 January 2010	Deletion of an assembler of the dosage form
•	16 December 2008	Change of composition of the immediate packaging Text layout changes to the SPC and Product Literature
•	29 October 2008	Change of legal category from MFX to POM-VPS Changes to the SPC and Product Literature to bring in line with new legislation
•	05 March 2008	Replacement of two manufacturing sites of the finished product
•	27 February 2008	Change of address of the MAH
•	02 November 2007	Replacement of two manufacturing sites for the finished product
•	09 October 2007	Change in batch size
•	30 November 2006	Minor change to the manufacturing process of the finished product
•	18 September 2006	Submission of a new Ph. Eur. Certificate of Suitability for an active substance
•	05 July 2006	Change of specification of the finished product Amendment of in-process controls performed during the manufacture of the finished product Minor change of manufacturing process of the finished product
•	28 June 2006	Renewal
•	05 June 2006	Change of address of the manufacturer and assembler of the dosage form Change of batch size
•	28 July 2005	Submission of a new Ph. Eur. Certificate of Suitability for an active substance
•	22 April 2004	Addition of a 12kg pack size