Veterinary Medicines Directorate

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Post Authorisation Assessments

Flubenol 5% w/w Premix for Medicated Feeding Stuff

Vm 00879/4179

•	18 January 2023	Submission of an updated certificate of suitability.
•	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 sites for QC testing of the finished product. Additional sites for QC testing of the finished product. Additional site for stability testing of the finished product. Deletion of a non-significant specification parameter for an excipient.
•	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	Change in specification of an active substance Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
•	07 March 2012	Change of distributor
•	26 April 2011	Addition of a retest period of 60 months and storage conditions ‘Do not store over 30˚C’for the active substance
•	21 February 2011	Submission of 2 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	Text layout changes to the SPC and Product Literature
•	27 November 2008	Addition of an immediate container

•	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
•	06 March 2008	Replacement of two manufacturing sites of the finished product
•	27 February 2008	Change of address of the MAH
•	02 November 2007	Minor change in the manufacture of the finished product
•	09 October 2007	Change in the batch size of the finished product
•	30 November 2006	Minor change in 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 to specification of the finished product Change to in process controls performed on the finished product Change of manufacturing process of the finished product
•	21 June 2006	Renewal
•	05 June 2006	Change in batch size of the finished product Change of address of a manufacturer and assembler of the dosage form
•	22 March 2006	Removal of the 10kg pack size
•	28 July 2005	Submission of a Ph. Eur. Certificate of Suitability for an active substance
•	22 December 2003	Renewal
•	14 June 2001	Change of name of manufacturing site of assembly Addition of a manufacturing site of assembly
•	20 January 1999	Change to safety warnings
•	18 November 1997	Addition of manufacturer of the active substance
•	20 March 1997	Renewal
•	26 March 1996	Change of withdrawal period for Meat from Pigs from 14 days to 7 days
•	18 September 1995	Change of importer Change of non-sterile containers Change to dosage particulars
•	31 May 1995	Change of name and address of the MAH
•	03 January 1995	Change of specification of the finished product