Veterinary Medicines Directorate

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Post Authorisation Assessments

Frontline Plus Spot-on Dog XL

Vm 08327/4271

•	13 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	16 June 2021	Addition to a test procedure for the finished product.
•	08 March 2021	Change in the number of units (pipettes) in a pack within the range of the currently approved pack sizes of the finished product. Change to part of the (primary) packaging material not in contact with the finished product formulation.
•	15 October 2020	Addition of a site where batch control/testing takes place.
•	19 August 2020	Renewal – national.
•	28 May 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	12 March 2020	Change in legal distribution category from NFA-VPS to AVM-GSL.
•	05 November 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	08 October 2019	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
•	15 April 2019	Update to the ASMF
•	12 February 2019	Change in the name and address of the manufacturer of the finished product.
•	16 November 2018	Change in the name and address of the marketing authorisation holder from Merial Animal Health Limited, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG, United Kingdom to Boehringer Ingelheim Animal Health UK Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom.
•	04 October 2018	Change in the address of a manufacturer of the active substance where no Ph. Eur. Certificate of Suitability is part of the approved dossier. Deletion of a manufacturing site for an active substance.
•	29 August 2018	Change in the address of the supplier used for the manufacture of the active substance. Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process of the active substance. Change of specification(s) of a former non Pharmacopoeial active substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State.

•	26 February 2018	Minor changes to an approved test procedure of the finished product. Minor change in the manufacturing process of the finished product.
•	27 November 2017	Changes to the labelling and/or package leaflet.
•	28 April 2017	Extension of a re-test period of the active substance.
•	10 February 2017	Approval of mock ups
•	10 March 2016	To change the legal category from POM-V to NFA-VPS
•	14 January 2016	Change in the QPPV and/or QPPV contact details and/or back-up procedure
•	22 December 2015	Change of invented product name