Veterinary Medicines Directorate

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Post Authorisation Assessments

Frontline Spot on Dog 10% w/v Spot on Solution

•	17 March 2021	Changes in the qualitative and quantitative composition of the immediate packaging (pipette) of the finished product.
•	05 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.
•	28 May 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	01 November 2018	Change in the name and address of the marketing authorisation holder from Merial Animal Health Ltd, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS.
•	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.
•	21 December 2017	Minor change in the manufacturing process of the finished product.
•	07 December 2017	Changes to the labelling and package leaflet.
•	01 November 2016	Addition of a secondary packaging site of the finished product.
•	20 November 2015	Change in legal distribution category from NFA-VPS to AVM-GSL. Deletion of an indication from the SPC.
•	27 March 2014	Change in the manufacture of the finished product at a manufacturing and release site.
•	26 March 2014	Deletion of a manufacturing site.
•	01 July 2008	Change of name and address of the head office and manufacturing site of the active substance
•	07 May 2008	Minor changes to the manufacturing process of the active substance
•	20 June 2007	Changes to the SPC and Product Literature to bring in line with new legislation

•	17 May 2006	Renewal
•	05 April 2006	Change of legal category from POM to NFA-VPS
•	14 January 2005	Addition of species ‘dog’ to the name on the product label
•	06 August 2004	Updates to the SPC and Product Literature
•	11 June 2004	Change of shelf life from 24 months to 36 months
•	29 May 2003	Change to test methods performed on the active substance
•	22 November 2002	Renewal
•	07 November 2002	Addition of a manufacturing site of the finished product
•	27 September 2002	Change of manufacturer of the active substance’s head office Change to specification of the active substance
•	06 September 2002	Change of safety warnings regarding use in pregnant and lactating dogs and puppies
•	01 October 2001	Change of contraindications regarding bathing before and after treatment Updates to section 5.7 of the SPC Addition of an indication against lice
•	12 January 2001	Minor change to manufacturing process of the active substance Change to specification of the active substance Change to manufacturer of the active substance
•	11 July 2000	Change of indications
•	02 June 2000	Change of type of non-sterile containers Change of manufacturer of the dosage form
•	29 October 1999	Changes to specification of the finished product Additional presentation of 1 pipette
•	12 August 1999	Update of licence particulars
•	08 August 1999	Addition of safety warnings and contraindication for use on rabbits
•	07 August 1999	Change of safety warnings
•	04 February 1999	Change of shelf life
•	20 November 1998	Additional presentations
•	03 March 1998	Change of size of sterile containers
•	06 March 1997	Change of MAH