Veterinary Medicines Directorate

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Post Authorisation Assessments

Nelio 2.5 mg Tablet for Cats

Vm 15052/4107

18 January 2025	Deletion of a Ph. Eur. CEP for an active substance. (NI).
January 2025	Submission of a new Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance. (GB).
16 August 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (GB)
15 August 2023	Change in qualitative or quantitative composition of the immediate packaging for a solid pharmaceutical form for a finished product.
14 March 2023	Deletion of a non-significant specification parameter in the specification parameters or limits of an excipient. Deletion of a non-significant specification parameter in the specification parameters or limits of an excipient. Deletion of a non-significant specification parameter in the specification parameters or limits of an excipient.
12 October 2022	Change in the address of the MAH from Unit 3 Anglo Office Park, White Lion Road, Amersham, Buckinghamshire, HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom.
07 January 2020	Minor changes to an approved test procedure of the finished product.
23 May 2019	Replacement of a site where batch control/testing takes place
22 November 2018	Replacement of a manufacturer responsible for batch release of the finished product. Deletion of a packaging site.
19 September 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
14 June 2017	Deletion of a non-significant specification parameter of an excipient.
18 May 2017	Deletion of a manufacturing site of an active substance.
10 November 2016	Change in name / address of a manufacturer of the finished product. Change in name / address of a manufacturer of the finished product. Change in name / address of a manufacturer of the finished product.
28 July 2016	Repeat use (UK comment only)
29 June 2016	Introduction of a new pharmacovigilance system which has been assessed by the relevant national competent authority/EMA for another product of the same MAH.

16 June 2016	Change of MAH, from Sogeval to Ceva Animal Health Ltd.
07 January 2016	Deletion of a manufacturing site of the active substance. Submission of a new or updated Ph. Eur. certificate of suitability. Submission of a new or updated Ph. Eur. certificate of suitability.
06 August 2015	Changes to the labelling and package leaflet. Change of distributor.
23 December 2014	Renewal.
21 December 2012	Implementation of changes to SPC and product literature in accordance with an EMA referral.
20 November 2012	Extension of finished product shelf life.
20 November 2012	Change in storage conditions of the finished product.
08 November 2012	To introduce a new retest period for the active substance.
13 July 2012	To submit a new Ph. Eur certificate of suitability from a new manufacturer of the active substance.
17 May 2010	To replace the site for primary packaging and add a supplementary site for secondary packaging.
25 March 2010	To replace the finished product manufacturer.