CaniLeish

Procedural steps taken and scientific information after the authorisation

No	Scope	Opinion / Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
R/0004	Renewal of the marketing authorisation	06/11/2015	07/01/2016	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for CaniLeish.
IB/0003	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	12/02/2015	n/a		The Agency accepted a variation to remove DTH test in mice from routine control tests on batches of finished product.
IB/0002	C.I.3.a - Implementation of change(s) requested following the assessment of an USR, class labelling, a PSUR, RMP, FUM/SO, data submitted under A 45/46, or amendments to reflect a Core SPC - Changes with NO new additional data are submitted by the MAH	10/01/2013		I,IIIB	The Agency accepted a variation to update the "Adverse Reactions" section of the SPC following reactions that have been observed at the injection site.

[1] Notifications are issued for type I variations (unless part of a group or a worksharing application). Opinions are issued for all other procedures.
[2] No Commission Decision is issued for type IA and type IB variations or for type II variations and annual re-assessments that do not affect the annexes.
[3] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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No	Scope	Opinion / Notification[4] issued on	Commission Decision Issued[5] / amended on	Product Information affected[6]	Summary
IB/0001	B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the currently approved batch size	13/04/2012			The Agency accepted a variation to increase the batch size of the active substance.

[4] Notifications are issued for type I variations (unless part of a group or a worksharing application). Opinions are issued for all other procedures.
[5] No Commission Decision is issued for type IA and type IB variations or for type II variations and annual re-assessments that do not affect the annexes.
[6] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).