

Veterinary Medicines Directorate Woodham Lane, New Haw Addlestone, Surrey KT15 3LS United Kingdom

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APPLICATION TO VARY A MARKETING AUTHORISATION: Variations <u>NOT</u> requiring assessment (VNRA)

An incomplete application form may delay the application process.

Further guidance about this application type is available on GOV.UK

Please note the following:

- 1. The list of VNRAs is available in online.
- 2. An application for a VNRA may only include <u>one change</u> to one MA, i.e. one product or one product range. The definition of a product range is included in the guidance on <u>GOV.UK</u>. NOTE - Products nationally authorised in NI and GB that are aligned (but have different MA numbers) are one MA for the purpose of this definition.

SECTION 1 – PRODUCT(S) TO BE VARIED

Authorisation Number	Product Name

Please add extra rows, if needed

VMD/L4/LAB/065/C #2213645 morrei/huntea

SECTION 2 – LABELLING AND SPC

If your variation affects the QRD (labelling or package leaflet text) and / or SPC, you do not need to provide updated versions with your application. We will update the latest versions and send these to you at the end of the application procedure.

Does your application affect the labelling, package leaflet and / or SPC? Yes D No D

SECTION 3 – COMMENTS

Is there anything else you would like to tell us?

SECTION 4 – SUPPORTING INFORMATION

4.1 Name and address of MAH:

MAH Name:	
MAH Address:	

4.2 Details of application contact:

Name:	
Telephone No.	
Email Address:	

The application contact <u>must</u> be registered as part of the company account in the Veterinary Medicines Digital Service (VMDS)

4.3 Purchase order number (if applicable):

4.4 Invoice email address:

If you have already provided these details to the VMD's finance team, you may leave this field blank.

SECTION 5 - DECLARATION

By ticking the 'agree' box, I confirm that the information provided in support of this application is correct at time of submission and all requirements have been fulfilled.

I understand that if any information provided in this application is later found to be false or incorrect, the Secretary of State may suspend or revoke the authorisation

AGREE 🗌

- Note:Not ticking this box will lead to your application being refused.
- If you can't fulfil all the requirements for the variation, your application will be refused and you will need to submit a new 'variation requiring assessment (VRA)' application form.
- Incomplete application forms will be rejected.
- You will be charged for refused applications.

ANNEX 1 – DETAILS OF CHANGE APPLIED FOR

Please complete the table below; an example is provided in red.

Category	Variation Reason	Present	Proposed	Implementation Date
A.1.a)	Change in the name and address of the marketing authorisation holder.	Current address is 51 Baker Avenue, Woking, GU21 3LS	New address is 74 Plum Pudding Road, Bristol, BR12 4RP.	31/12/2021
·····,			Name remains unchanged.	