



ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES

REQUEST FOR SPECIFIC BATCH CONTROL

Please note: an incomplete form will lead to your request being returned to you.

Product name:	Name and address of MA/ATC holder:
Active substance(s)/quantitative	Contact:
Pharmaceutical form:	E-mail address: Telephone number: Fax number: Supervisory Authority:
MA/ATC number: Applicants reference:	

A fee for each affected batch is required.

Number of batches affected:

Fee enclosed (Yes/No):

***(For Official Use Only)* NOTIFICATION TO APPLICANT**

- On the basis of the information and material you have submitted, the Competent Authority would not expect to take regulatory action to instigate a recall, or otherwise prohibit the supply of the product should the batch(es) in question be placed on the market, if the steps listed in the box below are carried when the batch(es) is/are placed on the market.
- On the basis of the information and material you have submitted, the Competent Authority anticipates that for the reasons set out in the box below it would be likely to take regulatory action either to instigate a recall or otherwise prohibit the supply of the product should the batch(es) in question be placed on the market.

Signed: _____

Date: _____

Contact: _____

STEPS/REASONS

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Product Name:

MA/ATC No:

RELATED APPLICATION(S) Please specify including date of pending renewal application(s)

SUMMARY OF BATCH DEVIATION

Please continue on a separate sheet if required.

BATCHES AFFECTED

Please complete the following information regarding the batches in question and append the Certificates of Analysis for each batch

BATCH TYPE*	BATCH NUMBER	DATE OF MANUFACTURE	BATCH SIZE

Please continue on a separate sheet if required.

* Specify whether the batch is active substance, excipient or final product

I REQUEST the VMD as competent authority to undertake specific batch control in respect of the above batches. I CERTIFY that, to the best of my knowledge, the deviation described in this request form and in the accompanying papers will not adversely affect the quality, efficacy or safety of the product.

Main Signatory:

Status (*Job title*):

Print name:

Date: