

[Your Company Letterhead]

[Date]

[Recipient Name]

[Recipient Title]

[MHRA Address]

[City, Postcode]

Dear [Recipient Name],

Subject: Variation Application for [Product Name / Product License Number]

We are writing to submit a variation application for [Product Name] under [specify variation type, e.g., Type IA, Type IB, or Type II] in accordance with the Medicines and Healthcare products Regulatory Agency (MHRA) guidelines.

****Product Details:****

- Product Name: [Product Name]

- Product License Number: [License Number]

- MA Holder: [Your Company Name]

****Type of Variation:****

- [Detail of the variation being applied for, e.g., changes to the product information, composition, packaging, etc.]

****Rationale for the Variation:****

[Briefly explain the reason for the variation and any supporting data or contextual information that may be relevant.]

****Supporting Documentation:****

[List the documentation included with this application, e.g., revised SmPC, labeling, batch records, etc.]

We trust that this submission will meet the requirements set forth by the MHRA and look forward to your timely feedback. Should you need any further information or clarification, please do not hesitate to contact us.

Thank you for your attention to this matter.

Yours sincerely,

[Your Name]

[Your Title]

[Your Company Name]

[Your Phone Number]

[Your Email Address]