VPA10804/001/001

ALPHA JECT 3000 Emulsion for injection for Atlantic salmon

Variation	Summary	Date
Vet - B3 f)	VNRA - Vet - B3 f) - - Vet - B3 f) - Changes to the quality part of the dossier: Deletion of one of the authorised bulk or final containers (including packaging of an active substance) or immediate packaging of the finished product that does not lead to the complete deletion of a strength or pharmaceutical form	21/01/26
Vet - B3 s)	VNRA - Vet - B3 s) - - Vet - B3 s) - Changes to the quality part of the dossier: Deletion of a supplier of packaging components or devices (when mentioned in the dossier)	21/01/26
Vet - G.I.15 z)	VRA-R - Vet - G.I.15 z) - - Vet - G.I.15 z) - Changes to the labelling or the package leaflet which are not connected with the summary of product characteristics - Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	15/09/25
Vet - G.I.18	VRA-S - Vet - G.I.18 - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 - G.I.18 Safety, Efficacy, Pharmacovigilance changes - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004	24/04/25
Vet - C6	VNRA - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17 - C6 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17	26/06/24
Vet - C1	VNRA - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV) - C1 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	26/06/24
Vet - F.II.b.1 e)	VRA-S - Vet - F.II.b.1 e) - e) Change in supplier of sterilised primary container components, which are to be used in the aseptic manufacture of veterinary medicinal products - F.II.b.1 e) Quality Changes - Finished Product -Manufacture - Replacement	31/01/23

	or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Change in supplier of sterilised primary container components, which are to be used in the aseptic manufacture of veterinary medicinal products	
Vet - F.I.a.2 z)	VRA-S - Vet - F.I.a.2 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.I.a.2 z) Quality Changes - Active Substance - Manufacture - Changes in the manufacturing process of the active substance - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	12/08/22
Vet - F.I.a.2 z)	VRA-S - Vet - F.I.a.2 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.I.a.2 z) Quality Changes - Active Substance - Manufacture - Changes in the manufacturing process of the active substance - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	12/08/22
B.I.a.1.z	IB - B.I.a.1.z - z Other variation - B.I.a.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Other variation	16/03/22
C.II.6.b	IB - C.II.6.b - b) Other changes - C.II.6.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - VETERINARY MEDICINAL PRODUCT ?SPECIFIC CHANGES - Changes to the labelling or the package leaflet which are not connected with the summary of product characteristics - Other changes	18/02/22