Floseal Hemostatic Matrix (Floseal VH S/D)

Procedural steps and scientific information after initial consultation

Application number	Scope	Opinion/ Notification[1] issued on	Summary
IA/0041	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	21/11/2023	Minor changes to an approved test procedure for the active substance.
IA/0040	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	16/05/2023	To submit a 2nd step notification procedure.
IB/0039	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	10/02/2023	The submission of the consolidated existing dossier module 3 with an updated module 2 to include the up-to-date changes submitted.

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.

IB/0037	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	28/09/2022	Minor change to the test procedure for the determination of endotoxin for Thrombin Bulk.
IB/0038	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	16/09/2022	Minor changes to a test procedure to introduce an additional sample preparation method.
IA/0036	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	23/08/2022	To submit a 2nd step notification procedure and change in the name of a vial manufacturer.
IA/0035/G	This was an application for a group of variations. Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	28/01/2022	Name change of manufacturing sites and update of a Ph. Eur. Certificate of Suitability.
IB/0034	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	08/10/2021	Change in batch size (including batch size ranges) of intermediate - The scale for a biological/immunological intermediate is increased without process change.
IAIN/0033	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	19/07/2021	To submit a 2nd step notification procedure.
IB/0032	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	10/05/2021	Change in the test procedure for the finished product.
IAIN/0031	B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP	24/07/2020	To submit a 2nd step notification procedure.

IAIN/0030/G	This was an application for a group of variations. Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	02/06/2020	To update the Ph. Eur. Certificate of Suitability and administrative update of the name of the manufacturer of the active substance. To submit a 2nd step notification procedure.
IAIN/0029	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	04/07/2019	To submit a 2nd step notification procedure.
IB/0028	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	25/03/2019	To delete the reference 'NF' (National Formulary of USP) for a reagent used in the manufacture of Human Thrombin VH S/D, ancillary medicinal substance of Medical Device Floseal Hemostatic Matrix (Floseal VH S/D).
IB/0027/G	This was an application for a group of variations. Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	25/02/2019	To change the Lot Numbering System for Thrombin VH S/D bulk (active substance) and Thrombin VH S/D (finished product).
IAIN/0025	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	21/06/2018	To submit a 2nd step notification procedure.
IB/0026	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	13/06/2018	To replace the test for the determination of Albumin in the finished product Thrombin. The acceptance criteria remain unchanged.
IAIN/0024	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	15/05/2017	To include a 2nd step notification procedure.
IB/0022	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	20/12/2016	Changes in the composition (excipients) of the currently used excipients finished product: replacement of a single excipient with a comparable excipient with the same functional

			characteristics and at similar level.
IA/0023	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	16/12/2016	Update of the Ph. Eur. certificates of suitability for an excipient.
IAIN/0021	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	19/08/2016	To submit a 2nd step notification procedure.
IA/0020	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	29/04/2016	To submit a 2nd step notification procedure.
IA/0019	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	02/06/2015	To tighten the in-process limits applied during the manufacture of the finished product and to submit a 2nd step notification procedure.
II/0018	Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II	21/05/2015	To replace one of the tests performed on the ancillary medicinal product.
X/0016	Annex I_2.(c) Change or addition of a new strength/potency	25/09/2014	Addition of a new strength of the ancillary medicinal product: 5000 IU Thrombin/vial (500 IU Thrombin/mL).
IA/0017	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	28/04/2014	To submit a 2nd step notification procedure.
II/0015/G	This was an application for a group of variations. Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	20/03/2014	To replace the immediate packaging of the diluent and introduce a new supplier and batch release site, to replace a device with CE mark which is not an integrated part of the primary packaging, to change the source of an excipient or reagent and to change the storage conditions of the finished product after reconstitution.

IB/0014	B.II.b.z - Change in manufacture of the Finished Product - Other variation	29/07/2013	Changes to the manufacturing process of the finished product.
IAIN/0013	B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP	10/06/2013	To submit a 2nd step notification procedure.
IAIN/0012	B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP	26/04/2013	To submit a 2nd step notification procedure.
IAIN/0011/G	This was an application for a group of variations. B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP A.5.b - Administrative change - Change in the name and/or address of a manufacturer of the finished product, including quality control sites (excluding manufacturer for batch release)	09/07/2012	To submit a 2nd step notification procedure and include an administrative change in the name/address of a manufacturer/supplier of the ancillary finished product.
IAIN/0010	B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes	08/12/2011	To submit a 2nd step notification procedure.

	do not affect the properties of the FP		
IA/0009/G	This was an application for a group of variations. B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information	25/10/2011	To delete a non-significant specification parameter for the active substance and change in the primary packaging material not in contact with the finished product formulation of the medicinal product.
IB/0007/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	09/08/2011	Minor changes in the test procedure for an excipient, the active substance and the finished product.
IA/0008/G	This was an application for a group of variations.	01/08/2011	To include the PMF Type II certificate and a 2nd step notification procedure.

	B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP		
IB/0005	B.II.b.z - Change in manufacture of the Finished Product - Other variation	20/01/2011	Changes to the manufacturing process of the finished product.
IB/0006	B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site	10/11/2010	To add a new site responsible for primary packaging for the finished product.
IB/0004	B.I.b.1.a - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits for medicinal products subject to Official Batch Release	26/07/2010	To tighten the specification limits for a medicinal product subject to Official Control Authority Batch release.
IB/0003	B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits	26/07/2010	To add new in process controls and limits for an intermediate of the active substance.
IA/0002	B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) -	15/07/2010	To submit a 2nd step notification procedure.

	Inclusion of an updated/amended PMF when changes do not affect the properties of the FP		
II/0001	Quality changes	19/11/2009	Changes to the storage of the active substance and changes to the manufacture of the finished product.