LifeGlobal Media

Procedural steps and scientific information after initial consultation

Application number	Scope	Opinion/ Notification [1] issued on	Summary
IA/0008	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	08/10/2024	To submit a 2nd step notification procedure.
IA/0007	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	25/08/2023	To update the legal manufacturer to CooperSurgical, Inc. and to reconfirm the Scientific Opinion granted under MDD (93/42/EEC) for the purpose of certification under MDR (MDR/2017/745).
IA/0006	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	08/03/2023	To submit a 2nd step notification procedure.
II/0005/G	This was an application for a group of variations.	23/02/2023	To add Instituto Grifols, S.A. as an alternative site responsible for manufacture of the active

[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.

	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II		substance human albumin; Minor changes in the manufacturing process of the finished product.
IB/0004	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	10/06/2021	
IB/0003	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	22/02/2021	To add Octapharma Pharmazeutika Produktionsges m.b.H, Oberlaaer Strasse 235, 1100 Vienna, Austria, as an alternative manufacturer and supplier of the ancillary medicinal substance, human albumin.
IA/0002	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	09/10/2020	To change the Notified Body from BSI Group (Kitemark Court, Davy avenue, Knowlhill, Milton Keynes, MK5 8 PP, United Kingdom) to BSI Group The Netherlands B.V. (Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands). To submit a 2nd step notification procedure. To change the address of the manufacturer and supplier of the ancillary medicinal substance, Octapharma AB, from Elersvagen 40, SE-112 75 Stockholm, Sweden to Lars Forssells gata 23, SE-112 75 Stockholm, Sweden.
IB/0001	B.II.z - Quality change - Finished product - Other variation	16/03/2018	To introduce an additional media: Global® total® LP (with 5% HSA), Global® total® LP for fertilization (with 5% HAS), Global® total® LP w/HEPES (with 5% HSA) and HSA (100 mg/ml in normal saline).