



08 February 2021  
EMA/80490/2021 Rev.1  
Human Medicines Evaluation Division

## COOK IVF cell culture media

### Procedural steps and scientific information after initial consultation

Application number	Scope	Opinion/ Notification <sup>1</sup> issued on	Summary
IA/0005	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	23/08/2018	To change the name of the manufacturer of the medical device from Cook Pharmica LLC (1300 S. Patterson Drive, Bloomington, IN 47403 USA) to Catalent Indiana LLC. The address remains unchanged.
IA/0004	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	19/10/2017	Change in the specification parameters and or/limits of the finished medicinal product of the ancillary medicinal substance.
IA/0003	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	11/11/2016	To delete William A. Cook Australia Pty. Ltd. 95 Brandl St, Brisbane Technology Park, Eight Mile

<sup>1</sup> 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.



			Plains, Queensland 4113, Australia, as a manufacturer of the medical device(s).
IB/0002	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	24/06/2015	To add Cook Pharmica LLC, 1300 S. Patterson Drive, Bloomington, Indiana 47403, USA as a new manufacturer of the medical device(s).
IB/0001	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	05/10/2012	Changes to a test procedure (including replacement or addition) for the ancillary substance in the medical device.