EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Evaluation Division

IVF Media G5 Series

Procedural steps and scientific information after initial consultation

Application number	Scope	Opinion/ Notification[1] issued on	Summary
II/0005	Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II	17/01/2013	To add Human Serum Albumin Solution 25% manufactured by Octapharma as alternative to the currently approved Human Serum Albumin Solution 25% manufactured by Grifols (previously Talecris) as ancillary medicinal substance.
IA/0006	A.4 - Administrative change - Change in the name and/or address of a manufacturer or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS	08/10/2012	To change the name of the Human Serum Albumin incorporated in the medical device from Talecris Biotherapeutics, Albumin (Human) 25% to Grifols Deutschland, Albumin (Human) 25%.

[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.

N/0004	Notification for ancillary medicinal substance in medical device	15/10/2008	
N/0003	Notification for ancillary medicinal substance in medical device	15/10/2008	
N/0002	Notification for ancillary medicinal substance in medical device	15/10/2008	
MF/0001	2PMF (2nd step of PMF certification procedure)	30/04/2008	