EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 February 2021
EMA/CHMP/105561/2021 Rev.1
Human Medicines Evaluation Division

Steen Solution

Procedural steps and scientific information after initial consultation

Application number	Scope	Opinion/ Notification[1] issued on	Summary
II/0002	Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II	17/01/2013	To add Albunorm (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/0003	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.

MF/0001	2PMF (2nd step of PMF certification procedure)	30/04/2008	