

From: [Lim, Agnes](#)
To: joan.robertson@grifols.com
Cc: sebastian.gascon@grifols.com; [Ananyeva, Natalya](#); [Do, Yu](#)
Subject: RE: BLA 125640/0; iPSP: Pediatric Study IG1405
Date: Monday, August 21, 2017 7:32:26 AM

Good Morning,

I am the clinical review for BLA 125640. Regarding the agreed iPSP (Pediatric study protocol IG1405), please submit a statement summarizing the grounds for deferring the studies, a brief description of the planned study, evidence that the study will be conducted with due diligence and at the earliest possible time, and a timeline for the completion of the study. Please contact me by email if you have any questions.

Please respond by email by 2:00pm EST today, 8/21/2017.

Regards,

Agnes Lim, M.D.
Medical Review Officer
Office of Cellular, Tissue, and Gene Therapy
Center for Biologics Evaluation and Research
Food and Drug Administration
WO71
Room 4320
10903 New Hampshire Ave.
Silver Spring, MD 20993
agnes.lim@fda.hhs.gov

"THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone."