

Our STN: BL 125683/0

**MID-CYCLE COMMUNICATION
AGENDA**

January 8, 2019

Grifols Therapeutics LLC
Attention: Joan Robertson
8368 US 70 Business Highway West
Clayton, NC 27520

Dear Ms. Robertson:

Attached is a copy of the agenda for your January 9, 2019, Mid-Cycle Communication Teleconference with CBER.

Please include a reference to STN BL 125683/0 in your future submissions related to the subject product.

If you have any questions, please contact me at (240) 402-8310.

Sincerely,

Cándido Alicea, Ph.D.
Regulatory Project Manager
Regulatory Management Staff
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research

Mid-Cycle Communication Teleconference Agenda

Application type and number: BLA 125683/0

Product name: Immune Globulin Subcutaneous (Human), 20%(b) (4)

Proposed Indication: Treatment of Primary Humoral Immunodeficiency (PI) in patients 2 years of age and older. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies

Applicant: Grifols Therapeutics LLC

Meeting date & time: January 9; 3:00 p.m.

Committee Chair: Jennifer Reed, Ph.D.

RPM: Candido Alicea, Ph.D.

Agenda:

Discussion Summary:

1. Any significant issues/major deficiencies, categorized by discipline, identified by the Review Committee to date.

The review team has no significant issues/major deficiencies to communicate at this time. The team has identified the need of a

- **PMC for stability final report**

Completion of all primary reviews projected to be before the Late Cycle meeting (4/5/19).

As specified in the FDA labeling guidance, please add section 13, Nonclinical Toxicology to the draft labeling for (b) (4).

<https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075082.pdf>

2. Information regarding major safety concerns.

There are no major safety concerns identified at this time.

3. Preliminary Review Committee thinking regarding risk management.

The review team has no further comments regarding risk management at this time.

4. Any information requests (IR) sent and responses not received.

**We are still waiting for a response to:
IR # 15 – Sent Dec 21, Clinical**

The delay in receiving your response may affect the review clock.

5. Any new information requests to be communicated.

Information Requests will be sent as needed to assist with the review.

6. Proposed date for the Late-Cycle meeting (LCM).

The LCM between you and the Review Committee is currently scheduled for April 5, 2019.

We intend to send the LCM meeting materials to you approximately 10 days in advance of the LCM.

If these timelines change, we will communicate updates to you during the course of the review.

7. Updates regarding plans for the AC meeting.

N/A

8. Other projected milestone dates for the remainder of the review cycle, including changes to previously communicated dates.

Labeling Target Date:	June 9, 2019
PMC Target Date:	June 9, 2019
First Action Due	July 9, 2019