



## LATE-CYCLE MEETING MATERIALS

Our STN: BL 125822/0

Kedrion SpA  
Attention: Erin Stokes, PhD  
Parker Plaza  
400 Kelby Street, 11<sup>th</sup> Floor  
Fort Lee, NJ 07024

Dear Dr. Stokes:

Please refer to your Biologic License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Immune Globulin Intravenous (Human) 10% 5 mg in 50 mL and 10 mg in 100 mL Solution.

Based on the progress of the review, we do not have any substantive review issues to discuss at this time. If you do not have any questions, additional data, or analyses to discuss for this application, the Late Cycle meeting may be cancelled upon your request. Please inform us in writing within two business days if you would like to cancel this meeting. If not, please identify your topics for discussion at the Late Cycle meeting.

If you have any questions, please contact the Regulatory Project Manager, Julia Wright at 301-796-4899 or by email at [julia.wright@fda.hhs.gov](mailto:julia.wright@fda.hhs.gov).

Sincerely,

Beatrice Kallungal, MS  
Director  
Division of Review Management and Regulatory Review 1  
Division of Review Management and Regulatory Review  
Office of Therapeutic Products  
Center for Biologics Evaluation and Research