



Our STN: BL 125590/0]

RESUBMISSION ACKNOWLEDGEMENT

October 15, 2018

ADMA Biologics
Attention: James Maloney
Senior Director, Regulatory Affairs
5800 Park of Commerce NW
Boca Raton, FL 33487

Dear Mr. Maloney:

This letter supersedes the correspondence dated October 12, 2018.

We have received your September 28, 2018, resubmission to your Biologics License Application (BLA) for Immune Globulin Intravenous (Human) 10% Liquid on October 1, 2018.

The resubmission contains CMC information that you submitted in response to our July 29, 2016, complete response letter.

We consider this a complete, Class 2 response to our action letter. Therefore, the action due date is April 2, 2019.

If you have any questions, please contact the Regulatory Project Manager, Patrick Riggins, at (240)402-8346.

Sincerely,

Basil Golding, MD
Director
Division of Plasma Protein Therapeutics
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research