



Our STN: BL 125668/o

**PROPRIETARY NAME ACCEPTABLE**

March 27, 2018

Octapharma Pharmazeutika Produktionsges.m.b.H.  
Attention: Mr. Stanley Ammons  
Octapharma USA Inc.  
121 River Street, Suite 1201  
Hoboken, NJ 07030

Dear Mr. Ammons:

We have reviewed your January 10, 2018, submission to your Biologics License Application (BLA) for Immune Globulin Subcutaneous (Human), requesting a proprietary name review for CUTAQUIG.

In consultation with Center for Biologics Evaluation and Research's Advertising and Promotional Labeling Branch, we conclude that, under the Federal Food, Drug, and Cosmetic Act and applicable regulations, CUTAQUIG is Acceptable.

If you have any questions, please contact the Regulatory Project Manager, Edward Thompson, at (240) 402-8443.

Sincerely,

Ramani V. Sista, PhD  
Director  
Division of Regulatory Project Management  
Office of Tissues and Advanced Therapies  
Center for Biologics Evaluation and Research