



Our STN: BL 125606/0

PROPRIETARY NAME ACCEPTABLE

CSL Behring GmbH
Attention: Mr. Kevin D. White
CSL Behring LLC
1020 First Avenue
PO Box 61501
King of Prussia, PA 19406-0901

Dear Mr. White:

We have reviewed your July 14, 2016, submission to your Biologics License Application (BLA) for C1 Esterase Inhibitor Subcutaneous (Human), requesting a proprietary name review for HAEGARDA.

In consultation with Center for Biologics Evaluation and Research's Advertising and Promotional Labeling Branch (CBER/APLB), we conclude that, under the Federal Food, Drug, and Cosmetic Act and applicable regulations, HAEGARDA, is acceptable.

If you have any questions, please contact the Regulatory Project Manager, Nannette Cagungun at (240) 402-8267 or nannette.cagungun@fda.hhs.gov.

Sincerely,

Basil Golding, MD
Director
Division of Hematology Research and Review
Office of Blood Research and Review
Center for Biologics Evaluation and Research