



Our STN: BL 125555/0

PROPRIETARY NAME ACCEPTANCE

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 submission dated June 5, 2014 to your biologics license application (BLA) for Antihemophilic Factor (Recombinant) requesting a proprietary name review.

In consultation with CBER's Advertising and Promotional Labeling Branch (APLB) we conclude that under the Federal Food, Drug, and Cosmetic Act and applicable regulations, your proposed proprietary name, NUWIQ is acceptable at this time.

We will perform another proprietary name review of NUWIQ closer to the time of the action due date to ensure that we have not approved a conflicting proprietary name for another product in the interim.

If you have any questions, please contact Dr. Jiahua Qian at (240) 402-8432

Sincerely,

Paul D. Mintz, MD
Director
Division of Hematology Clinical Review
Office of Blood Research and Review
Center for Biologics
Evaluation and Research