

From: [Dehdashti, Seameen \(Jean\)](#)
To: ["BDV \(Barbara Davies\)"](#)
Cc: [Dehdashti, Seameen \(Jean\)](#)
Subject: BLA 12567/0: FDA Review of Proposed 4-letter Suffix
Date: Thursday, May 17, 2018 8:24:01 AM
Attachments: [image001.png](#)

Good morning Barbara,

We find the proper name, antihemophilic factor (recombinant), glycoPEGylated-exei, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, antihemophilic factor (recombinant), glycoPEGylated-exei, will be the proper name designated in the license, and you should revise your proposed labels and labeling accordingly. However, please be advised that if your application receives a complete response, the acceptability of your proposed suffix will be re-evaluated when you respond to the deficiencies. If we find your proposed proper name unacceptable upon our re-evaluation at that time, we will inform you of our finding.

Please confirm receipt of this e-mail communication, and do not hesitate to contact me, should you have any questions and/or concerns.

Warm regards,

Jean Dehdashti, MSc, RAC
Regulatory Project Manager

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