

From: [Jarvis, Candace](#)
To: ["Michelle Meng \(michelle.meng@bayer.com\)"](#)
Cc: [Jarvis, Candace](#); [Owosela, Olukayode \(Kay\)](#); [Sauna, Zuben](#); [Stockbridge, Lisa L](#)
Subject: BLA 125661/0 Bayer Healthcare Suffix Review
Date: Wednesday, March 21, 2018 4:22:09 PM
Attachments: [image002.png](#)

Good afternoon Dr. Meng,

Please refer to your BLA Application submitted on August 30, 2017.

We find the proper name, antihemophilic factor (recombinant), PEGylated-aucl, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, antihemophilic factor (recombinant), PEGylated-aucl, 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 let me know if you have any questions.

Confirm receipt.

Regards,

Candace N. Jarvis
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