

From: [Dehdashti, Seameen \(Jean\)](#)
To: "BDV (Barbara Davies)"
Cc: [Dehdashti, Seameen \(Jean\)](#)
Subject: FDA Information Request (IR) RE Nonproprietary Naming of Biological Products: BLA 125671/0
Date: Thursday, April 05, 2018 2:04:04 PM
Attachments: [Nonproprietary Naming of Biological Products Guidance for Industry - UCM....pdf](#)
[image002.png](#)
Importance: High

Good afternoon Barbara,

Reference is made to Novo Nordisk, Inc., original BLA 125671 submission, dated February 27, 2018. The FDA review team is requesting the information outlined below in **bold text**. Please provide your response by close of business (COB), Friday, April 20, 2018, and please notify me, if you are not able meet the proposed due date.

FDA Information Request: Nonproprietary Naming of Biological Products

Your application falls within the scope of the guidance entitled Nonproprietary Naming of Biological Products (please see attached pdf document), which states that, for certain biological products, the FDA intends to designate a four-letter distinguishing suffix that is devoid of meaning. Certain provisions of the guidance, relating to the collection of information, are still under review by the Office of Management and Budget under the Paperwork Reduction Act of 1995. However, provisions that do not describe the collection of information should be considered final, including the description of the naming convention and the considerations that support the convention, which reflects FDA's current thinking on the nonproprietary naming convention.

We are informing you of the designated proper name for your product and that FDA intends to assign a four-letter suffix for inclusion in the proper name designated in the license, if your product is approved. If you so choose, you are welcome to submit proposed suffixes for FDA's consideration. Please see attached guidance for additional information on the naming convention and guidelines for proposed suffixes.

The suffix will be added to the designated proper name of your product, in the format shown below.

Antihemophilic Factor (Recombinant), GlycoPEGylated-XXXX

Please confirm receipt of my e-mail, 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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