



Our STN: BL 125611/0

**PROPRIETARY NAME UNACCEPTABLE**

Novo Nordisk  
Attention: Ms. Patricia Wilson  
August 3, 2016  
Sent by email

Dear Ms. Wilson

We have reviewed your June 21, 2016, amendment to your Biologics License Application (BLA) for Coagulation Factor IX (Recombinant), Pegylated, requesting a proprietary name review for (b) (4)

In consultation with the 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, (b) (4) is Unacceptable for the following reason:

1. Your proposed name may cause medication error due to its high phonetic and orthographic similarity to other medicinal products, including RIFADIN, RIFAMPIN, ROFOLINYN, and ROCEPHIN.

You may submit a new proprietary name for our consideration. Any proposed proprietary name should comply with the regulations regarding false, misleading, or fanciful names, and regarding phonetic or orthographic similarities to other medicinal products.

If you require additional information on developing proprietary names for drugs, we refer you to the following: Draft Guidance for Industry *Best Practices in Developing Proprietary Names for Drugs*, and Guidance for Industry *Contents of a Complete Submission for the Evaluation of Proprietary Names*.

You may request reconsideration of (b) (4) by submitting a written rebuttal with supporting data and/or submitting a request for a Type C meeting within 60 days to discuss the initial decision. Additional information regarding submission of a meeting request may be found in the Guidance for Industry *Formal Meetings with Sponsors and Applicants for PDUFA Products* (May 2009).

If you have any questions, please contact the Regulatory Project Manager, Edward Thompson at (240) 402-8443.

Sincerely yours,

Howard Chazin, MD., MBA  
Acting Director  
Division of Hematology Clinical Review  
Office of Blood Research and Review  
Center for Biologics Evaluation and Research