

## BIMO Filing Checklist

Application Information	
<b>BLA/NDA Number:</b>	<b>125611-0</b>
<b>Proprietary Name:</b>	<b>nonacog beta pegol (INN designated name)</b>
<b>Established/Proper Name:</b>	<b>Coagulation Factor IX (Recombinant), GlycoPEGylated</b>
<b>Proposed indication(s):</b>	<b>Use in adults and children with hemophilia B for control and prevention of bleeding episodes, perioperative management, and routine prophylaxis</b>
<b>Applicant:</b>	<b>Novo Nordisk, Inc.</b>
<b>Submission Date:</b>	<b>6/3/2016</b>
<b>Date of Filing Meeting:</b>	<b>7/15/2016</b>
<b>Filing Date:</b>	<b>8/2/2016</b>
<b>Action Due Date:</b>	<b>5/16/2017</b>
<b>Reviewer:</b>	<b>Anthony Hawkins</b>
<b>Reviewer's Division:</b>	<b>OCBQ/DIS/Bioresearch Monitoring (BIMO)</b>

**IS THE APPLICATION FILEABLE?**  X  Yes /     No

If the application is not fileable from the BIMO Reviewer's perspective, state the rationale for your recommendation and provide letter ready comments to be sent to the Applicant.

**Rationale:**

1. N/A

Please identify and list any potential review issues in letter ready comment format to be forwarded to the Applicant in the filing letter or the Deficiency Identified (DI) letter (74-day letter).

1. N/A

## C 910.08: BIMO Filing Checklist

Items Required for Review and Assessment of BIMO-fileable / Not-fileable	Required item found?		Comments
	Yes	No (Explain in Comments)	
Complete listing of all clinical studies submitted in support of the Marketing Application	X		
Complete listing of all study sites for all clinical studies submitted, identified by: <ul style="list-style-type: none"> <li>• Clinical Investigator name</li> <li>• Address</li> <li>• Telephone number</li> <li>• Study site number/other unique site identifier</li> </ul>	X		
Clinical protocol(s) for all clinical studies submitted, including each of the corresponding study reports	X		
Clinical study data generated by each site for all clinical studies submitted, presented in a verifiable format (line listings/datasets) identifiable by individual study site and individual subjects within each dataset. <u>Example data tables:</u> <ul style="list-style-type: none"> <li>• Protocol Violations/Deviations</li> <li>• Adverse Events</li> <li>• Demographics</li> <li>• Data specific to submission type and study conducted including all study endpoints</li> </ul>	X		

**\*\* Notify the review committee as soon as possible upon noting any missing BIMO review items from the above checklist, prior to the committee established Refuse to File deadline. Communicate all specific missing BIMO review items still needed for BIMO to consider the submission-fileable.**

## C 910.08: BIMO Filing Checklist

### BIMO FILING REVIEW CONCURRENCE

**Application number:** STN 125611-0

---

BIMO Reviewer

Date

I concur with the reviewer(s) recommendation? \_\_\_\_ Yes / \_\_\_\_ No If no, provide a justification.

---

Branch Chief

Date

I concur with the reviewer(s) recommendation? \_\_\_\_ Yes / \_\_\_\_ No If no, provide a justification.

---

Division Director

Date