

FILING MEETING AGENDA/SUMMARY

Application number: STN 125611/0
Applicant: Novo Nordisk Inc.
Product name: Coagulation Factor IX (Recombinant), GlycoPEGylated
Proposed Indication: Indicated for use in adults and children with hemophilia B for:

- Control and prevention of bleeding episodes
- Perioperative management
- Routine prophylaxis

Meeting date & time: July 15, 2016, 12:30 P.M.
Committee Chair: Chava Kimchi-Sarfaty
RPM/Meeting Recorder: Edward Thompson

Background: Product name and indications were summarized. The observation of accumulated PEG in the brain was mentioned and will be discussed further.

Table 1: Review Committee and Discipline Filing Decision Summary

Discipline/Organization	Name [with credentials (not title)]	Attended meeting	Fileable	RTF	Deficiencies Identified
Regulatory Project Manager	Edward Thompson	X	X		
Regulatory Project Manager	Mark Levi	X	X		
Chair	Chava Kimchi-Sarfaty	X	X		
Division Director/Deputy	Michael Kennedy	X	X		
Clinical Reviewer	Megha Kaushal	X	X		
Clinical Pharmacology Reviewer	Iftekhar Mahmood		X		
Toxicology Reviewer	La’Nissa Brown-Baker	X	X		
CMC Reviewer	Aikaterini Alexaki	X	X		
CMC Reviewer	Nobuko Katagiri		X		
OCBQ/DMPQ Reviewer	Kevin Foley		X		
OCBQ/DMPQ/PRB Reviewer	Jacqueline Glen		X		
OCBQ/APLB Reviewer	Kristine Khuc/ Proxy - Sonny Saini	X	X		
OCBQ/BIMO Reviewer	Anthony Hawkins	X	X		
OCBQ/DBSQC Reviewer	Marie Anderson	X	X		
OCBQ/DBSQC Reviewer	Hsiaoling Wang	X	X		
OCBQ/DBSQC Reviewer	Grainne Tobin	X	X		
OCBQ/DBSQC Reviewer	Kouassi Ayikoe	X	X		
OCBQ/DBSQC Reviewer	Simleen Kaur	X	X		
OCBQ/DMPQ/Team Lead	Pete Amin	X	X		
Statistical Reviewer	Judy Li	X	X		

Discipline/Organization	Name [with credentials (not title)]	Attended meeting	Fileable	RTF	Deficiencies Identified
Postmarketing Safety Epidemiological/Pharmacovigilance Reviewer	Ravi Goud	X	X		
Other Attendee(s)	Renee Rees	X	X		
	Lokesh Bhattacharyya	X	X		

REGULATORY CONCLUSIONS / DEFICIENCIES

1. Does the application, on its face, appear to be suitable for filing or is the application unsuitable for filing and will require a RTF letter?

FILEABLE

2. If fileable, list any substantive deficiencies or issues that have significant impact on the ability to complete the review or approve the application:

Dr. Ravi Goud [Division of Epidemiology] – the inclusion of a PDP for PEG accumulation; this information will not be included in the filing. An information request will be submitted for this information.

3. If RTF, list any issues that would make this application unsuitable for filing?

NA

FILING MEETING DISCUSSION:

4. Indicate any comments on the status of the proprietary name review.

Review on-going with APLB.

5. Indicate whether the product sh/would be subject to lot release, surveillance, or exempt from lot release.

Decision is pending. Meeting scheduled for July 21, 2016 with DBSQC, CMC reviewers and RPM.

6. What is the review classification of this application?

Standard Review

7. Indicate the decision regarding the need for an Advisory Committee.

This application may be submitted for BPAC. Discussion continues regarding the PEG accumulation in the brain.

8. Indicate whether the submission triggers PREA; if yes, a PeRC meeting is needed.

Yes. The PeRC meeting is scheduled for December 14, 2016.

9. Is a comprehensive and readily located list of all clinical sites included or referenced in the application?

Yes, as described within the individual clinical study reports (Appendix 16)

10. Is a comprehensive and readily located list of all manufacturing facilities included or referenced in the application?

Yes, as described within Section 2.3.A.1.

11. Indicate any updates since the first committee meeting on pre-license inspection, pre-approval inspection, or BIMO sites requiring inspections (Is the establishment(s) ready for inspection?)

Facilities inspection waiver is pending.

BIMO is currently drafting a clinical investigator inspection assignment covering approximately 3-4 study sites under Phase 3 protocol NN7999-3747, for subsequent review/concurrence by the clinical reviewer.

12. If the application is affected by the Application Integrity Policy (AIP), has the division made a recommendation regarding whether or not an exception to the AIP should be granted to permit review based on medical necessity or public health significance?

NA

13. Is the product an Original Biological Product or a New Molecular Entity (NME), for NDAs only?

Decision pending

FOR APPLICATIONS IN THE PROGRAM (PDUFA V) (NME NDAs/Original BLAs)

14. Confirm that any late submission components were submitted within 30 days. List any late submission components that arrived after 30 days.

NA

15. Was the application otherwise complete upon submission, including those applications where there were no agreements regarding late submission components?

Complete

ADMINISTRATIVE DETAILS:

16. Review the Milestone Schedule and indicate if there are any issues with the schedule. Note: This is a confirmation to capture any changes made since the first committee meeting.

None

17. Enter the date of the Mid-cycle Meeting, if appropriate (required for NME NDAs/BLAs in “the Program” PDUFA V):

Internal Mid-Cycle Meeting date is November 10, 2016 at 12 noon.

END

History

Drafted	Edward Thompson/ July 15, 2016
Revised	Mark Levi/ July 15, 2016
Revised	Chava Kimchi-Sarfaty/July 18, 2016, August 2, 2016
Revised	Simleen Kaur/ July 18, 2016
Revised	Anthony Hawkins/ July 18, 2016
Revised	Megha Kaushal/ July 18, 2016
Revised	Ravi Goud/ July 19, 2016
Revised	Kevin Foley/ July 25, 2016