Our STN: BL 125466/243

SUPPLEMENT APPROVAL
PMR/PMC FULFILLED
November 30, 2018

Novo Nordisk Inc.
Attention: Ms. Darshana Malavade
P.O. Box 846
800 Scudders Mill Road
Plainsboro, NJ 08536

Dear Ms. Malavade:

We have approved your request dated January 31, 2018, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262) for Antihemophilic Factor (Recombinant) [NOVOEIGHT] to update the indication from "control and prevention of bleeding episodes" to "on-demand treatment and control of bleeding episodes" and to present your data from Studies NN7008-3568 and NN7008-3809 into your prescribing information label.

LABELING

Under 21 CFR 201.57(c)(18), patient labeling must be referenced in section 17 PATIENT COUNSELING INFORMATION. Patient labeling must be available and may either be reprinted immediately following the full prescribing information of the package insert or accompany the prescription product labeling.

We hereby approve the draft package insert labeling submitted under amendment 14, dated November 30, 2018.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71–G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes these changes.

FULFILLED POSTMARKETING REQUIREMENT/COMMITMENTS

This submission fulfills your postmarketing commitment identified in the October 15, 2013, approval letter for BLA STN BL 125466/0 for Antihemophilic Factor (Recombinant). The commitment addressed in this submission is as follows:

PMC #1 Novo Nordisk commits to evaluate the safety and efficacy of Novoeight in previously untreated patients with hemophilia A in Trial NN7008-3809, Safety and efficacy study in prevention and treatment of bleeds in pediatric previously untreated patients with Hemophilia A.

- Study/trial completion date: September 30, 2016

- Final Study Report submission date: March 31, 2017

PEDIATRIC REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and

effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We note that you have fulfilled the pediatric study requirement for all relevant pediatric age groups for this application.

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

Tejashri Purohit-Sheth, MD
Director
Division of Clinical Evaluation and
Pharmacology/Toxicology
Office of Tissue and Advanced Therapies
Center for Biologics Evaluation and Research