

CBER REGULATORY REVIEW MEMORANDUM

Date January 3, 2019

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DIVISION OF REGULATORY PROJECT MANAGEMENT (DRPM)
Office of Tissues and Advanced herapies (OTAT)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

To Biologics License Application Submission Tracking Number # 125671/0

Subject NDC Code Review Memo for Antihemophilic Factor
(Recombinant), GlycoPEGylated-exei

Through Erica Giordano, Chief (Acting), DRPM, OTAT

Applicant Novo Nordisk, Inc.

Product Antihemophilic Factor (Recombinant), GlycoPEGylated-exei
[ESPEROCT]

Biologics License Application (BLA) Submission Tracking Number (STN) 125671/0

Submission Received by CBER February 27, 2018

Review Completed January 3, 2019

Material Reviewed NDC labeler codes as submitted in the draft of Highlights of Prescribing Information and draft Carton and Container labels

Background

On February 27, 2018, Novo Nordisk submitted BLA 125671/0 for their Antihemophilic Factor, GlycoPEGylated B-domain deleted recombinant human factor VIII (rFVIII) with a ^{(b) (4)} kilodalton polyethylene-glycol-maleimide conjugated to the protein. It is indicated for use in previously treated adults and adolescents (12 years of age and older) with hemophilia A (congenital factor VIII deficiency) for 1) on-demand treatment and control of bleeding episodes; 2) perioperative management of bleeding; and 3) routine prophylaxis to reduce the frequency of bleeding episodes.

Antihemophilic Factor (recombinant), GlycoPEGylated-exei [ESPEROCT] is formulated as a sterile lyophilized powder for reconstitution with 0.9% sodium

chloride solution as diluent for intravenous administration. ESPEROCT is available in single use glass vials of 500, 1,000, 1,500, 2,000, or 3,000 international units (IU) in (b) (4) fill size. The drug product is reconstituted with a prefilled syringe of (b) (4) 0.9% sodium chloride solution.

The National Drug Code (NDC) assignments to the product presentations for the ESPEROCT drug product vial, kit components, and carton packaging have been reviewed and are in compliance with NDC labeling requirements for all three NDC segments, as per *FDA/CBER draft job aid, JA 900.08: National Drug Code and Bar code Labeling Review*. Please see table below of the NDC assignments for all proposed product presentations as listed under Section 16, How Supplied/Storage and Handling of the draft Highlights of Prescribing Information, and supplied draft Carton and Container labels:

TABLE 1. ESPEROCT Vial, Carton, and Components NDC Labeler Codes

Presentation (Nominal Product Strength)	Carton NDC Numbers	Components
500 IU	NDC 0169 8500 01	<ul style="list-style-type: none"> • ESPEROCT in single-use vial [NDC 0169 8501 11] • Pre-filled sterile saline diluent in syringe, 4 mL [NDC 0169 8008 98] • Vial adapter
1000 IU	NDC 0169 8100 01	<ul style="list-style-type: none"> • ESPEROCT in single-use vial [NDC 0169 8101 11] • Pre-filled sterile saline diluent in syringe, 4 mL [NDC 0169 8008 98] • Vial adapter
1500 IU	NDC 0169 8150 01	<ul style="list-style-type: none"> • ESPEROCT in single-use vial [NDC 0169 8151 11] • Pre-filled sterile saline diluent in syringe, 4 mL [NDC 0169 8008 98] • Vial adapter
2000 IU	NDC 0169 8200 01	<ul style="list-style-type: none"> • ESPEROCT in single-use vial [NDC 0169 8201 11] • Pre-filled sterile saline diluent in syringe, 4 mL [NDC 0169 8008 98] • Vial adapter
3000 IU	NDC 0169 8300 01	<ul style="list-style-type: none"> • ESPEROCT in single-use vial [NDC 0169 8301 11] • Pre-filled sterile saline diluent in syringe, 4 mL [NDC 0169 8008 98] • Vial adapter

Executive Summary

A review of existing NDC labeler codes (outlined in Table 1) was completed as per *FDA/CBER draft job aid, JA 900.08: National Drug Code and Bar code Labeling Review*. I verify that the information outlined below are correct and appropriately assigned:

- The *first* segment of the NDC labeler code was verified through PRPLLR application.
- The *second* segment of the NDC labeler code, the product code, are uniquely assigned to the product for every listed presentation (nominal product strength) of ESPEROCT.
- The *third* segment of the NDC labeler code, the product presentation, are uniquely assigned to the vial and carton labels, as illustrated in Table 1.

A review of the carton NDC labeler codes, that constitutes the kit (i.e., comprised of ESPEROCT in single-use vial at 500, 1000, 1500, 2000, or 3000 IU, a pre-filled sterile saline diluent in syringe, 4 mL, and a Vial adapter) verified that unique NDC labeler codes have been assigned at the kit level. Furthermore, for every kit configuration, the vial containing the active component (ESPEROCT) and syringe diluent have a unique NDC labeler code assigned. Please note that the NDC labeler code for the pre-filled sterile saline diluent in syringe, 4 ml (NDC 0169 8008 98), supplied in the kit components, is identical and correctly listed for all presentations of ESPEROCT. The vial adapter included in the kit does not have an NDC labeler code listed, as this component is regulated as a Medical Device.

Furthermore, a review of the NDC labeler codes as printed on the carton and container labels are consistent with the NDC labeler codes listed in the SPL, under Section 16, How Supplied/Storage and Handling of the draft Highlights of Prescribing Information.

I recommend approval of the NDC codes.