



NDA 208583/S-001

SUPPLEMENT APPROVAL

Novo Nordisk Inc.
Attention: Rick Spring
Associate Director, Regulatory Affairs
800 Scudders Mill Road
Plainsboro, NJ 08536

Dear Mr. Spring:

Please refer to your supplemental New Drug Application (sNDA) dated and received December 4, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Xultophy 100/3.6 (insulin degludec and liraglutide injection).

This Prior Approval sNDA provides for proposed modifications to the approved Xultophy 100/3.6 risk evaluation and mitigation strategy (REMS). This supplement is in response to our December 1, 2017, REMS Modification Notification letter.

We have completed our review of this supplemental application. It is approved effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Xultophy 100/3.6 was originally approved on November 21, 2016. The REMS consists of a communication plan and a timetable for submission of assessments of the REMS. In order to minimize burden on the healthcare delivery system of complying with the REMS, we determined that you were required to make the REMS modifications outlined in our REMS Modification Notification letter dated December 1, 2017.

Communication Plan: We have determined that the communication plan is no longer necessary as an element of the REMS to ensure the benefits of Xultophy 100/3.6 outweigh its risks because available REMS assessment data for other members of the GLP-1 agonist class that are indicated for the treatment of type 2 diabetes mellitus demonstrate acceptable knowledge of the risks of pancreatitis and medullary thyroid carcinoma, suggesting that these risk messages have been communicated to the relevant prescriber groups. No assessment of the current communication plan is needed.

Therefore, because the communication plan is no longer necessary to ensure the benefits of the drug outweigh the risks, a REMS is no longer required for Xultophy 100/3.6.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Marisa Petruccelli, Regulatory Project Manager, at (240) 402-6147.

Sincerely,

{See appended electronic signature page}

Jennifer Rodriguez Pippins, M.D., M.P.H.
Deputy Director for Safety
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

MARY T THANH HAI
12/12/2017