



NDA 022341/S-029

SUPPLEMENT APPROVAL

Novo Nordisk, Inc.
Attention: Michelle Thompson
Senior Director, Regulatory Affairs
P.O. Box 846
800 Scudders Mill Road
Plainsboro, New Jersey 08536

Dear Ms. Thompson:

Please refer to your Supplemental New Drug Application (sNDA) dated and received July 19, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Victoza (liraglutide) injection.

This sNDA provides for proposed modifications to the approved risk evaluation and mitigation strategy (REMS). This supplement is in response to our July 18, 2017, REMS Modification Notification letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Victoza (liraglutide) injection was originally approved on January 25, 2010, and the most recent modification was approved on September 20, 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 following REMS modifications: elimination of the communication plan as an element of the REMS.

Because the communication plan has been completed and the assessment demonstrates that the communication plan has met its goals, we have determined that it is no longer necessary to include it as an element of the approved REMS to ensure that the benefits of the drug outweigh the risks.

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 Victoza (liraglutide) injection.

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/

JENNIFER R PIPPINS
07/26/2017