DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022341/S-021

SUPPLEMENT APPROVAL

Novo Nordisk, Inc.
Attention: Robert B. Clark
VP Regulatory Affairs
P.O. Box 846
800 Scudders Mill Road
Plainsboro, NJ 08536

Dear Mr. Clark:

Please refer to your Supplemental New Drug Application (sNDA) dated and received October 10, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Victoza (liraglutide [rNDA origin] injection).

We acknowledge receipt of your amendments dated March 26, May 12, June 13, July 1, 14, and 24, 2014.

This supplemental new drug application provides for proposed modifications to the approved risk evaluation and mitigation strategy (REMS) for Victoza to modify the communication plan to include additional communications for healthcare providers that address the potential risk of medullary thyroid carcinoma and the risk of acute pancreatitis. This supplement is in response to our REMS Modification Notification letter dated August 14, 2013.

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

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Victoza was originally approved on January 25, 2010, and was last modified on May 18, 2011. The REMS consists of a communication plan and a timetable for submission of assessments of the REMS. Your proposed modifications to the REMS consist of:

1. Revision of the REMS goal statement
2. Revision of the Communication Plan
    - Replacement of the Dear Healthcare Provider letter with a REMS Letter for Healthcare Providers and a REMS Letter for Professional Societies
    - Addition of a REMS Factsheet
    - Addition of REMS Slides

- Dissemination of REMS information at scientific meetings
- Revision of the Victoza REMS website to reflect the aforementioned changes

3. Revision of the timetable for submission of REMS assessments
4. Revision of REMS assessment plan

Your proposed modified REMS, submitted on July 24, 2014, and appended to this letter, is approved.

The revised REMS assessment plan should include, but is not limited to the following:

a. An evaluation of the implementation of REMS Communication Plan activities:
   i. Launch date of revised communication plan
   ii. Number of HCPs and professional societies targeted by the REMS.
   iii. REMS Letter: Number of REMS letters sent to HCPs and Professional Societies via US mail (or email if this method is added) and the dates the letters were sent. Number of letters that were undeliverable will be included. Provide a list of names of professional societies with date of confirmed REMS letter receipt, along with any actions taken (e.g., posting on societies website, other outreach to members regarding REMS letters).
   iv. REMS Factsheet: number of HCPs detailed and provided the REMS Factsheet through the detail.
   v. REMS Slides: number of presentations employing the REMS Slides during the reporting period and cumulatively and number of attendees (including targeted physicians).
   vi. Scientific meetings: list of scientific meetings where Novo Nordisk Medical Information has a presence (e.g., booth) in which the Victoza REMS Factsheet was made available.
   vii. REMS website: Date when the revised REMS website went live and number of unique site visits during the assessment period and cumulative.

b. Evaluation of HCPs knowledge
   i. An evaluation of HCPs' knowledge of potential risk of medullary thyroid carcinoma and the risk of acute pancreatitis (including necrotizing pancreatitis) associated with Victoza. Stratify results by type of HCP (general/family/internal medicine).
   ii. An evaluation of prescribers' awareness of REMS materials.
   iii. An evaluation of prescribers' sources of knowledge about the risks associated with Victoza.

c. Safety Surveillance and Utilization Data for the reporting period and cumulatively
   i. Victoza total prescription data by HCP target (PCP/IM, NP/PA, OBGYN, Other).

ii. A summary and analysis of all postmarketing case reports of (a) pancreatitis and (b) medullary thyroid carcinoma.

d. Evaluation of the extent to which the elements of the REMS are meeting the goals and objectives of the REMS and whether modifications to the elements or goals and objectives are needed.

In addition to the assessments submitted according to the timetable included in the approved REMS, you must submit a REMS assessment when you submit a supplemental application for a new indication for use as described in section 505-1(g)(2)(A) of the FDCA.

If the assessment instruments and methodology for your REMS assessments are not included in the REMS supporting document, or if you propose changes to the submitted assessment instruments or methodology, you should update the REMS supporting document to include specific assessment instrument and methodology information at least 90 days before the assessments will be conducted. Updates to the REMS supporting document may be included in a new document that references previous REMS supporting document submission(s) for unchanged portions. Alternatively, updates may be made by modifying the complete previous REMS supporting document, with all changes marked and highlighted. Prominently identify the submission containing the assessment instruments and methodology with the following wording in bold capital letters at the top of the first page of the submission:

NDA 022341 REMS CORRESPONDENCE
(insert concise description of content in bold capital letters, e.g.,
UPDATE TO REMS SUPPORTING DOCUMENT - ASSESSMENT METHODOLOGY)

An authorized generic drug under this NDA must have an approved REMS prior to marketing. Should you decide to market, sell, or distribute an authorized generic drug under this NDA, contact us to discuss what will be required in the authorized generic drug REMS submission.

Prominently identify the submission containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission as appropriate:

NDA 022341 REMS ASSESSMENT

NEW SUPPLEMENT FOR NDA 022341
PROPOSED REMS MODIFICATION

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 022341
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

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, please call Pooja Dharia, Pharm.D., Regulatory Project Manager, at (301) 796-5332.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURES:
REMS

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JENNIFER R PIPPINS
07/31/2014