DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022341/S-007
NDA 022341/S-009
NDA 022341/S-013

SUPPLEMENT APPROVAL

Novo Nordisk Inc.
Attention: Anne Phillips, M.D.
Corporate Vice President, CMR
100 College Road West
Princeton, NJ 08540

Dear Dr. Phillips:

Please refer to your Supplemental New Drug Applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Victoza (liraglutide [rDNA origin] injection).

SUPPLEMENT NUMBER:	S-007	S-009	S-013
DATE OF SUBMISSION:	June 8, 2011	June 30, 2011	October 6, 2011
DATE OF RECEIPT:	June 8, 2011	June 30, 2011	October 6, 2011

We acknowledge receipt of your amendments dated:

S-007: September 9, October 21, December 7, 2011, and March 5, April 6, 2012
S-009: August 2, September 19, 22, 27, October 3, 2011, February 8, 22, and March 2, April 6, 2012
S-013: April 6, 2012

These "Prior Approval" supplemental new drug applications provide for the following:

1) Revisions to the Physician Insert (PI) based on the efficacy and safety results from Study NN2211-1860, entitled *The Effect of Liraglutide Compared to Sitagliptin, Both in Combination with Metformin in Subjects with Type 2 Diabetes. A 26-Week, Randomised, Open-label, Active Comparator, Three-Armed, Parallel-Group, Multi-Centre, Multi-National Trial With a 52-Week Extension* (S-007),

2) Revisions to the PI based on the efficacy and safety results from Study NN2211-1842, entitled *The Effect of Insulin Detemir in Combination with Liraglutide and Metformin Compared to Liraglutide and Metformin in Subjects with Type 2 Diabetes. A 26-week, Randomized, Open-label, Parallel-group, Multicentre, Multinational Trial with a 26-week Extension* (S-009), and

3) Revisions to the PI and Medication Guide based on postmarketing reports of serious hypersensitivity reactions, including anaphylactic reactions and angioedema (S-013).

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

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(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

REPORTING REQUIREMENTS

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

We request that for a period of two years, you submit an annual summary report in your periodic safety update report of all product quality issues (malfunctions and complaints) with the autoinjector pen. The summary report should provide details of any modifications or corrective actions to or for the device, and also include any trending analysis conducted.

Additionally, we request that for a period of two years, you submit all cases of hemorrhagic and/or necrotizing pancreatitis and all cases of suspected or confirmed reports of acute pancreatitis with an outcome of death as 15-day alert reports, and that you provide analyses of clinical trial and post-marketing reports of pancreatitis, including hemorrhagic and/or necrotizing pancreatitis, as adverse events of special interest in your periodic safety update reports.

If you have any questions, please call Pooja Dharia, Pharm.D., Regulatory Project Manager, at (301) 796-5332.

Sincerely,

{See appended electronic signature page}

Mary Parks, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURES:
Package Insert
Medication Guide

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

/s/

AMY G EGAN
04/06/2012
Amy Egan for Mary Parks