DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20933

NDA 19-938/S-063
NDA 19-959/S-066
NDA 19-991/S-067

SUPPLEMENT APPROVAL

NovoNordisk Inc
Attention: Mary Ann McElligott, Ph.D.
Associate Vice President, Regulatory Affairs
100 College Road West
Princeton, NJ 08540

Dear Dr. McElligott:

Please refer to your supplemental new drug applications dated and received June 6, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NDA/Supplement Number	Name of Drug Product
19-938/S-063	**Novolin R, Regular, Human Insulin Injection (rDNA origin) USP**
19-959/S-066	**Novolin N, NPH, Human Insulin Isophane Suspension (rDNA origin)**
19-991/S-067	**Novolin 70/30, 70% NPH, Human Insulin Isophane Suspension and 30% Regular, Human Insulin Injection (rDNA origin)**

We acknowledge receipt of your submissions dated March 19, 2008.

These supplemental new drug applications provide for the following changes: reduction of reading grade level, addition of in-use storage conditions to the Novolin R, Novolin N, and Novolin 70/30 Patient Package Inserts (PPIs), and standardization of the Novolin R, Novolin N, and Novolin 70/30 Instructions for Use Leaflets (IFULs) for the approved 10mL Vial presentation.

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described

at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling text for the Patient Package Inserts submitted on March 19, 2009, and the 10mL Vial Instructions For Use Leaflets submitted on June 6, 2008. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate these submissions **"SPL for approved NDA 19-938/S-063, NDA 219-959/S-066, NDA 19-991/S-067"** respectively.

PROMOTIONAL MATERIALS

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

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about these drug products (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letters to both the NDAs and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Suite 12B05
Rockville, MD 20857

If you have any questions, call Rachel Hartford, Regulatory Project Manager, at (301) 796-0331.

Sincerely,

{See appended electronic signature page}

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

Enclosures:
Novolin R - Patient Package Insert
Novolin R - 10mL Vial Instructions for Use Leaflet
Novolin N - Patient Package Insert
Novolin N - 10mL Vial Instructions for Use Leaflet
Novolin 70/30 - Patient Package Insert
Novolin 70/30 - 10mL Vial Instructions for Use Leaflet

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

/s/

Mary Parks

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