DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 019938/S-067 and S-069
NDA 019959/S-069 and S-071
NDA 019991/S-070 and S-072
NDA 020986/S-058 and S-060

SUPPLEMENT APPROVAL

Novo Nordisk 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 (sNDAs) dated and received December 8, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for:

- NDA 019938/S-069 - Novolin R (human insulin [rDNA origin] injection)
- NDA 019959/S-071 - Novolin N (human insulin [rDNA origin] isophane suspension)
- NDA 019991/S-072 - Novolin 70/30 (70% human insulin [rDNA origin] isophane suspension and 30% human insulin [rDNA origin] injection)
- NDA 020986/S-060 - Novolog (insulin aspart [rDNA origin] injection).

These sNDAs provide NovoPen Junior carton labels listing Denmark as the manufacturing site for NovoPen Junior. The NovoPen Junior was approved on April 11, 2002 under NDA 019938/S-032, NDA 019959/S-034, NDA 019991/S-035, and NDA 020986/S-004. Approval did not include carton labels.

We also refer to your sNDAs dated and received July 16, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for:

- NDA 019938/S-067 - Novolin R (human insulin [rDNA origin] injection)
- NDA 019959/S-069 - Novolin N (human insulin [rDNA origin] isophane suspension)
- NDA 019991/S-070 - Novolin 70/30 (70% human insulin [rDNA origin] isophane suspension and 30% human insulin [rDNA origin] injection)
- NDA 020986/S-058 - Novolog (insulin aspart [rDNA origin] injection).

We acknowledge receipt of your amendments dated September 25 and October 9, 2009, and March 25 and May 27, 2010.

These sNDAs provide for a new manufacturing site for NovoPen Junior in Tianjin, China.

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

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your December 8, 2009, submission containing final printed carton labels with the manufacturing site for the NovoPen Junior listed as Denmark. We also acknowledge your March 25, 2010, submission containing final printed carton labels with the manufacturing site for the NovoPen Junior listed as China.

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.

As required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. 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.

Please submit one market package of the drug product when it is available.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

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 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:
NovoPen Jr. Carton Label – Yellow (Denmark)
NovoPen Jr. Carton Label - Green (Denmark)
NovoPen Jr. Carton Label – Yellow (China)
NovoPen Jr. Carton Label - Green (China)

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20986	SUPPL-60	NOVO NORDISK INC	Aspart (NOVOLOG)
NDA-20986	SUPPL-58	NOVO NORDISK INC	Aspart (NOVOLOG)
NDA-19991	SUPPL-72	NOVO NORDISK INC	NOVOLIN 70/30
NDA-19991	SUPPL-70	NOVO NORDISK INC	NOVOLIN 70/30
NDA-19959	SUPPL-71	NOVO NORDISK INC	NOVOLIN N
NDA-19959	SUPPL-69	NOVO NORDISK INC	NOVOLIN N
NDA-19938	SUPPL-69	NOVO NORDISK INC	NOVOLIN R
NDA-19938	SUPPL-67	NOVO NORDISK INC	NOVOLIN R

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/s/

MARY H PARKS
06/25/2010