NOVO NORDISK A S
Form 6-K
October 08, 2003

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SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

Report of Foreign Issuer Pursuant to Rule 13a-16 or 15d-16

of the Securities Exchange Act of 1934

8 October 2003

NOVO NORDISK A/S

(Exact name of Registrant as specified in its charter)
Novo Allé
DK- 2880, Bagsvaerd
Denmark

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F

Form 20-F __X__ Form 40-F ____

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes ____ No __X__

If Yes is marked, indicate below the file number assigned to the registrant in connection with Rule 12g-32(b):82-_____

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf of the undersigned, thereunto duly authorized.

NOVO NORDISK A/S

Date: 8 October 2003

Lars Rebien Sørensen,
President and Chief Executive Officer

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Stock Exchange Announcement

8 October 2003

Novo Nordisk receives Approvable Letter for insulin detemir from the FDA

Novo Nordisk has received an Approvable Letter from the US Food and Drug Administration (FDA) for insulin detemir, a long-acting insulin analogue for the treatment of diabetes. In the letter the FDA requests that Novo Nordisk addresses certain clinical issues and provides additional information before US marketing approval can be granted. Novo Nordisk is working with the agency to clarify and resolve outstanding issues. The implications for the timeline of the US approval process are contingent upon the outcome of the discussions with the FDA.

Novo Nordisk will provide an update on the approval process in the US and Europe in connection with the release of its financial statement for the first nine months of 2003 on 29 October. Furthermore, Novo Nordisk expects to provide an update of the timeline for the US approval in connection with the release of the financial statement for 2003 on 5 February 2004, pending completion of the consultations with the FDA.

Insulin detemir was submitted to the FDA and the European Medicines Evaluation Agency (EMEA) for registration in the fourth quarter of 2002.

Insulin detemir belongs to a new class of basal insulin analogues with a neutral pH and unique mechanism for prolonging action (protraction). Currently available basal insulin preparations may produce variable blood glucose responses to the same dose given on different days. The distinct chemical structure of insulin detemir allows for a slower and more stable absorption from the injection site[(1)]. In clinical trials, the overall frequency and pattern of adverse events was similar to NPH (Neutral Protamine Hagedorn) insulin.

FORWARD-LOOKING STATEMENT

The above sections contain forward-looking statements as the term is defined in the US Private Securities Litigation Reform Act of 1995. Forward-looking statements provide current expectations or forecasts of events such as new product introductions, product approvals and financial performance.

Such forward-looking statements are subject to risks, uncertainties and inaccurate assumptions. This may cause actual results to differ materially from expectations. Factors that may affect future results include interest rate and currency exchange rate fluctuations, delay or failure of development projects, production problems, unexpected contract breaches or terminations, government-mandated or market-driven price decreases for Novo Nordisk s products, introduction of competing products, Novo Nordisk s ability to successfully market both new and existing products, exposure to product liability and other lawsuits, changes in reimbursement rules and governmental laws and related interpretation thereof, unexpected growth in costs and expenses.

Risks and uncertainties are further described in reports filed by Novo Nordisk with the US Securities and Exchange Commission (SEC) including the company s Form 20-F, which was filed on 27 March 2003. Please also refer to the section Financial Risk Factors in the Annual Financial Report 2002. Novo Nordisk is under no duty to update any of the forward-looking statements or to conform such statements to actual results, unless required by law.

Novo Nordisk is a focused healthcare company. With the broadest diabetes product portfolio in the industry, including the most advanced products within the area of insulin delivery systems, Novo Nordisk is a world leader in diabetes care. In addition, Novo Nordisk has a leading position within areas such as haemostasis management, growth hormone therapy and hormone replacement therapy. Novo Nordisk manufactures and markets pharmaceutical products and services that make a significant difference to patients, the medical profession and society. With headquarters in Denmark, Novo Nordisk employs approximately 18,500 people in 68 countries and markets its products in 179 countries. Novo Nordisk s B shares are listed on the stock exchanges in Copenhagen and London. Its ADRs are listed on the New York Stock Exchange under the symbol NVO . For further company information visit www.novonordisk.com

Novo Nordisk A/S
Corporate Communications

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(1) Heise T, Nosek L, Draeger E, Stender A, Rønn BB, Heinemann L, Kapitz C. Lower within-subject variability of insulin detemir in comparison to NPH insulin and insulin glargine in subjects with type 1 diabetes. Poster 518-P, presented at: 63rd annual meeting of the American Diabetes Association, June 14, 2003, New Orleans, LA, USA.

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