NOVO NORDISK A S
Form 6-K
June 08, 2012

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
Pursuant to Rule 13a-16 or 15d-16
of the Securities Exchange Act of 1934

June 8, 2012

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-_____

Company Announcement

8 June 2012

FDA extends regulatory review period for insulin degludec and insulin degludec/insulin aspart by three months

Novo Nordisk today announced that the US Food and Drug Administration (FDA) has extended the regulatory review period for the ultra-long-acting insulins degludec and insulin degludec/insulin aspart for the treatment of type 1 and type 2 diabetes.

The FDA informed Novo Nordisk that a three-month extension was required in order to complete its review of the new drug applications (NDA) for the two insulins.

During the review period the FDA has asked for further data clarification and analyses. In response, Novo Nordisk has submitted a substantial amount of additional data. Due to the size and timing of these submissions the FDA considers them as major amendments to the NDAs. The agency has not requested additional clinical trials.

Novo Nordisk submitted the NDAs to the FDA on 29 September 2011, and with the extension of the review the action date is now 29 October 2012.

About insulin degludec and insulin degludec/insulin aspart

Insulin degludec is a once-daily, ultra-long-acting basal insulin analogue discovered and developed by Novo Nordisk. Insulin degludec has a distinct slow absorption which provides a flat and stable action profile. Insulin degludec has been studied in a large-scale clinical trial programme, BEGIN™, examining its impact on glucose control, hypoglycaemia and the possibility to flexibly adjust insulin degludec dosing time to suit patient needs.

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Insulin degludec/insulin aspart contains the ultra-long-acting basal insulin degludec in a formulation with a bolus boost of insulin aspart. Insulin degludec/insulin aspart is the first and only soluble insulin combination of ultra-long-acting insulin degludec and the most prescribed rapid acting insulin, NovoRapid® (NovoLog® in the US) providing both fasting and post-prandial glucose control.

Insulin degludec and insulin degludec/insulin aspart have been submitted to the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) in September 2011 for regulatory review. In addition, applications have been submitted for regulatory approval in Japan, Canada, Switzerland and a range of other countries.

Novo Nordisk is a global healthcare company with 89 years of innovation and leadership in diabetes care. The company also has leading positions within haemophilia care, growth hormone therapy and hormone replacement therapy. Headquartered in Denmark, Novo Nordisk employs approximately 33,000 employees in 75 countries, and markets its products in more than 190 countries. Novo Nordisk's B shares are listed on NASDAQ OMX Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit novonordisk.com.

Further information:

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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.

Date: June 8, 2012

NOVO NORDISK A/S

Lars Rebien Sørensen,

President and Chief Executive Officer