

NOVO NORDISK A S
Form 6-K
September 08, 2016

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

September 2, 2016

NOVO NORDISK A/S

(Exact name of Registrant as specified in its charter)

Novo Allé

DK- 2880, Bagsvaerd

Denmark

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(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 ☒ 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 ☒

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

FDA extends regulatory review period for IDegLira by three months

Bagsværd, Denmark, 2 September 2016 - Novo Nordisk today announced that the US Food and Drug Administration (FDA) has extended the regulatory review period for IDegLira, the fixed-ratio combination of insulin degludec and liraglutide in adults with 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 application (NDA) for IDegLira.

Novo Nordisk submitted the NDA to the FDA in September 2015, and with the extension of the review the action date is now expected in December 2016.

Further information

Media:

Katrine Sperling	+45 3079 6718	krsp@novonordisk.com
Ken Inchausti (US)	+1 609 786 8316	kiau@novonordisk.com

Investors:

Peter Hugrefte Ankersen	+45 3075 9085	phak@novonordisk.com
Melanie Raouzeos	+45 3075 3479	mrz@novonordisk.com
Hanna Ögren	+45 3079 8519	haoe@novonordisk.com
Kasper Veje (US)	+1 609 235 8567	kpvj@novonordisk.com

		Internet:
Novo Nordisk A/S	Novo Allé	Telephone:
	2880 Bagsværd	+45 4444 8888
Investor Relations	Denmark	CVR no:
		24 25 67 90
		Company announcement No 60 / 2016

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: September 6, 2016

Lars Rebien Sørensen.

Chief Executive Officer