NOVO NORDISK A S
Form 6-K
March 30, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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FORM 6-K

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REPORT OF FOREIGN PRIVATE ISSUER

Pursuant to Rule 13a-16 or 15d-16

of the Securities Exchange Act of 1934

March 29, 2017

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NOVO NORDISK A/S

(Exact name of Registrant as specified in its charter)

Novo Allé

DK- 2880, Bagsvaerd

Denmark

(Address of principal executive offices)

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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-_____

Novo Nordisk resubmits new drug application for fast- acting insulin aspart in the US

Bagsværd, Denmark, 29 March 2017 – Novo Nordisk today announced that the company has resubmitted the new drug application (NDA) for fast-acting insulin aspart as a class II re-submission to the US Food and Drug Administration (FDA).

In October 2016, Novo Nordisk announced that it had received a Complete Response Letter from the FDA regarding the NDA for fast-acting insulin aspart. In the letter, the FDA requested additional information related to the assay for the immunogenicity and the assay used to generate the clinical pharmacokinetics data before the review of the NDA could be completed. Novo Nordisk has now evaluated the content of the Complete Response Letter and completed the End-of-Review meeting with FDA; based on this, Novo Nordisk has resubmitted the fast-acting insulin aspart NDA as a class II re- submission.

Novo Nordisk expects to receive feedback from the FDA in the last quarter of 2017.

About fast-acting insulin aspart

Fast-acting insulin aspart is a mealtime insulin for the control of postprandial glucose excursions in type 1 and type 2 diabetes as well as in pump treatment. Fast-acting insulin aspart is insulin aspart (NovoLog®/NovoRapid®) in a new formulation in which two new excipients have been added to ensure early and fast absorption. Fast-acting insulin aspart received marketing authorisation from the European Commission on 9 January 2017, covering all 28 European Union member states. Approvals were also received in Norway, Iceland and Canada. It is also currently under regulatory review in Switzerland, Australia, Brazil, South Africa, Argentina and Israel.

About Novo Nordisk

Novo Nordisk is a global healthcare company with more than 90 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat other serious chronic conditions: haemophilia, growth disorders and obesity. Headquartered in Denmark, Novo Nordisk employs approximately 42,000 people in 77 countries and markets its products in more than 165 countries. For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube

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.

NOVO NORDISK A/S

Date: March 29, 2017

Lars Fruergaard Jørgensen

Chief Executive Officer