

## **Novo Nordisk US shares skid on drug review setback (Update)**

February 11 2013, by Tom Murphy

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Shares of Novo Nordisk tumbled Monday after the Danish drugmaker said U.S. regulators need a new study before they can finish their review of two diabetes treatments, a development that could delay approval for several years.

The company said Sunday that the Food and Drug Administration wants to see information from a study that looks at cardiovascular health before it makes a decision on Tresiba and Ryzodeg, which both use the long-acting insulin degludec.

Novo Nordisk said it was surprised and disappointed by the decision. The company plans to provide the requested data, but it probably will not be able to do so this year.

The request could delay U.S. approval by up to five years, Jefferies analyst Jeffrey Holford said in a research note.

European regulators approved Tresiba and Ryzodeg last month, and the drugs also have been approved in Japan and Mexico.

An FDA panel of endocrinology experts had voted 8-4 in favor of approving the drugs in November, or more than a year after Novo Nordisk submitted its application. The panelists also voted unanimously that the drugmaker should be required to conduct a cardiovascular study due to concern about possible heart safety side effects.

But the panelists recommended that the trial should be conducted after approval.

The FDA is not required to follow the advice of its panels, but it often does.

The FDA also told Novo Nordisk it cannot approve the drugs until the company resolves some manufacturing violations the agency outlined in a recent warning letter. The Dec. 12 letter said an inspection of the company's drug-making factory in Denmark found significant violations of good manufacturing practices.

The letter accused the company of not establishing or following appropriate written procedures for preventing contamination of sterile drug products.

Diabetes is a chronic condition in which the body either does not make enough insulin to break down the sugar in foods or uses insulin inefficiently. It can cause early death or serious complications like blindness, a stroke, kidney disease or heart disease when blood sugar climbs too high and damages organs and blood vessels.

Demand for drugs that treat diabetes is climbing as rising instances of obesity are causing an explosion of diabetes cases globally.

Degludec is an insulin that can last more than 42 hours, which helps diabetics control their blood sugar levels beyond the 24-hour period offered by current products on the market. This means patients can maintain good blood sugar control even if they don't take it at the same time every day.

U.S.-traded shares of Novo Nordisk tumbled more than 13 percent, or \$25.61, to \$166.68 in midmorning trading Monday. They have traded in

a 52-week range of \$129.41 to \$194.44.

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