

Danish drugmaker reaches settlement with US authorities

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Danish drug maker Novo Nordisk says it has reached a \$46.5 million settlement with U.S. authorities over allegations that it hadn't properly communicated safety information when marketing a medicine to treat type 2 diabetes.

Novo Nordisk says it also will pay \$12.15 million to resolve a complaint filed by the government on behalf of the U.S. Food and Drug Administration in federal court.

Douglas Langa, head of Novo Nordisk's North America operations, said late Tuesday that the Copenhagen-based company denies "any wrongdoing" but was pleased with the case's resolution.

The Department of Justice said the settlement resolved allegations that Novo Nordisk failed to comply with the FDA-mandated Risk Evaluation and Mitigation Strategy for its Type II diabetes medication.

It said U.S. authorities had required Novo Nordisk to provide information regarding the potential risk of a rare form of cancer associated with the drug named Victoza, which was approved by the FDA in 2010.

The Department of Justice said "Novo Nordisk sales representatives gave information to physicians that created the false or misleading impression" that the FDA-mandated warning "was erroneous, irrelevant, or unimportant."

The "actions unnecessarily put vulnerable patients at risk," said Channing D. Phillips, U.S. Attorney for the District of Columbia. "We have sent a strong signal to the drug industry today."

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