Medtronic Diabetes receives FDA warning letter

DUBLIN, Dec. 15, 2021 /PRNewswire/ -- Medtronic plc (NYSE:MDT) today announced it received a warning letter from the U.S. Food and Drug Administration (FDA) on December 9 for the company's Northridge, California, facility, the headquarters for its Diabetes Business. The warning letter was issued following an inspection that concluded in July 2021 related to recalls of the MiniMed™ 600 series insulin infusion pump, and a remote controller device for MiniMed™ 508 and Paradigm™ pumps.

The warning letter focuses on the inadequacy of specific medical device quality system requirements at the Northridge facility in the areas of risk assessment, corrective and preventive action, complaint handling, device recalls, and reporting of adverse events.

"We are committed to fully resolving all observations as effectively and quickly as possible. Nothing is more important to us than providing the highest quality products to people living with diabetes," said Sean Salmon, executive vice president and president of the Diabetes business at Medtronic.

To ensure the most effective response to the warning letter, Medtronic will apply resources from across the company and utilize external experts. The company is implementing a range of corrective actions and process improvements related to the observations, and will continue reviewing these actions with the FDA.

Medtronic is not recommending any action by patients or their healthcare providers as a result of this warning letter.

"Every day millions of people living with diabetes around the world rely on the innovations we deliver, and Medtronic remains deeply committed to ensuring their safety and well-being," said Salmon.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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