Medtronic News

Medtronic Receives FDA Warning Letter Following Inspection of Its Mounds View, Minn. Facility

FDA Noted that the Company's Promised Corrective Actions Appear to be Adequate to Resolve the Issues Raised in the Letter

MINNEAPOLIS--(BUSINESS WIRE)--Nov. 18, 2009-- Medtronic (NYSE: MDT) today announced it received a warning letter from the U.S. Food and Drug Administration (FDA) regarding the inspection of the Company's Mounds View, Minn. (Cardiac Rhythm Disease Management) facility completed in August 2009.

The FDA's observations fall into four general categories: corrective and preventive action (CAPA) and field action timeliness; review and documentation of field action recommendations; supplier qualification and controls; and medical device reporting (MDR) timeliness.

"Medtronic remains committed to providing the highest quality products to our customers and is working with FDA to resolve all remaining issues as quickly as possible," said Pat Mackin, president of the Cardiac Rhythm Disease Management business and senior vice president at Medtronic.

The Company will respond to the letter within 15 days, as required. In addition, the Company has already begun to implement changes and put procedures in place related to each of the observations cited during the inspection, and any additional actions that may be required will be in place as quickly as possible. FDA noted in its warning letter to Medtronic that the Company's promised corrective actions appear to be adequate to address the concerns raised in the letter and will be confirmed upon reinspection.

No action is required by patients or physicians as a result of this letter.

About Medtronic

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology – alleviating pain, restoring health, and extending life for millions of people around the world.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's Annual Report on Form 10-K for the year ended April 24, 2009. Actual results may differ materially from anticipated results.

Source: Medtronic, Inc.

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