Medtronic News

Medtronic Resolves FDA Warning Letters

MINNEAPOLIS, Mar 09, 2011 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE:MDT) today announced that the U.S. Food and Drug Administration (FDA) has informed the company that issues noted in two warning letters -- one from November 2009 regarding the company's Mounds View, Minnesota facility and another from June 2009 regarding the company's manufacturing facility in Juncos, Puerto Rico -- have been resolved.

"We are encouraged that the action plans implemented by our teams have resolved the observations identified by the FDA in both warning letters," said William A. Hawkins, chairman and chief executive officer of Medtronic. "We will continue to provide the highest quality products and we are actively working to ensure the changes we have made are appropriately incorporated across all of our global facilities. We have developed a culture of prevention and accountability across our entire enterprise and we will continue to invest aggressively in the continuous improvement of our people, processes and products."

Medtronic received an FDA warning letter following an August 2009 inspection of the company's Mounds View facility, which serves as the headquarters of the Cardiac Rhythm Disease Management business. The company also received an FDA warning letter following a December 2008 inspection of the company's facility in Juncos, which is a manufacturing location for the Neuromodulation, Diabetes and Cardiac Rhythm Disease Management businesses.

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 periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

SOURCE: Medtronic, Inc.

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