FDA News Release

FDA enters consent decree with Medtronic, Inc.

Company cited for manufacturing violations

April 27, 2015

Release

The U.S. Food and Drug Administration announced today the filing of a consent decree against Medtronic, Inc., and two of the company's officers—S. Omar Ishrak and Thomas M. Tefft —for repeatedly failing to correct violations, related to the manufacture of Synchromed II Implantable Infusion Pump Systems, medical devices that deliver medication to treat primary or metastatic cancer, chronic pain and severe spasticity. These violations occurred at the company's Neuromodulation facilities in Columbia Heights, Minnesota, where the devices are manufactured.

The consent decree cites violations of the quality system regulation for medical devices, which requires manufacturers to have processes in place to assure that the design, manufacture and distribution of a device allows for its safe use.

The legal action requires the company to stop manufacturing, designing and distributing new Synchromed II Implantable Infusion Pump Systems except in very limited cases, such as when a physician determines that the Synchromed II Implantable Infusion Pump System is medically necessary for a patient's treatment.

The consent decree also requires Medtronic to retain a third-party expert to help develop and submit plans to the FDA to correct violations. The consent decree will remain in effect until the FDA has determined that Medtronic has met all the provisions listed in the consent decree.

Once Medtronic receives permission from the FDA to resume the design, manufacture and distribution of these products, the company must continue to submit audit reports so the agency can verify the company's compliance. In addition to these audits, the FDA will monitor the company's activities through its own inspections.

The FDA first approved the Synchromed II Implantable Infusion Pump Systems in 2004, and first identified problems with the manufacture of these pumps in 2006. These problems can result in over- or under-infusion or a delay in therapy for patients.

Between 2006 and 2013, FDA investigators conducted five inspections at Medtronic's Neuromodulation facilities, resulting in three warning letters notifying the company of major

violations. The violations included inadequate processes for identifying, investigating, and correcting quality problems with the Synchromed II Implantable Infusion Pump Systems; failure to document design changes; and failure to ensure that finished products meet design specifications.

“The FDA expects that all patients will be treated with safe, effective and high-quality medical devices,” said Jan Welch, acting director of the Office of Compliance in the FDA’s Center for Devices and Radiological Health. “We will continue to stop distribution of devices made by firms that fall short of regulatory requirements.”

Patients who are implanted with a Synchromed II Implantable Infusion Pump System should maintain regular follow-up appointments with their physicians. Patients who experience a change or return of symptoms, or hear a device alarm, should contact their physician immediately.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety and effectiveness of human and veterinary drugs, biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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