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Replace GenStrip blood glucose test strips

Patients with diabetes and health care professionals should stop using GenStrip Blood Glucose Test Strips because the strips may report incorrect blood glucose levels, according to the Food and Drug Administration (FDA).

A recent FDA inspection turned up extensive violations of federal regulations in the manufacturing of the test strips from Shasta Technologies LLC.

GenStrip Blood Glucose Test Strips are “third-party” blood glucose monitoring test strips advertised for use with the LifeScan OneTouch family of glucose meters (e.g. Ultra, Ultra 2 and Ultra Mini).

The FDA is advising patients and others to obtain alternative glucose test strips designed for use with the LifeScan OneTouch glucose

meters. A warning letter was sent to Shasta on April 8, but to date, the company has been unwilling to voluntarily recall its test strips, resulting in their continued availability.

Adverse reactions or problems experienced with the use of GenStrip Glucose Test Strips should be reported to the FDA at www.fda.gov/Safety/MedWatch/HowtoReport/default.htm or by calling 800-332-1088.

Read the FDA MedWatch safety alert, with a link to the safety communication, at: www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm395270.htm.