



March 1, 2010

RECALL: OneTouch SureStep Test Strips (LifeScan)

Read the complete MedWatch 2010 Safety summary, including a link to the firm's press release, at:
<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm202254.htm>

LifeScan and FDA notified healthcare professionals of a voluntary recall of eight lots of OneTouch SureStep Test Strips, used by people with diabetes to measure their blood glucose levels at home. The test strips are being recalled because they may provide falsely low glucose results when the glucose level is higher than 400 mg/dL.

If patients use the falsely low test results to determine their insulin dose, they may give themselves too little insulin, which could result in poor blood glucose control. High blood glucose must be recognized and treated promptly to avoid serious complications, such as coma and death.

The eight lots of consumer OneTouch SureStep Test Strips being recalled are identified in the firm's press release. Lot numbers are located on the outer carton and test strip vial. LifeScan estimates approximately fourteen thousand packages (50- and 100-count) of consumer OneTouch SureStep Test Strips were distributed nationwide between August 1, 2009 and January 28, 2010.

It is important that patients with recalled test strips continue to test their blood glucose. Patients with access to a meter that does not use OneTouch SureStep Test Strips should use this other meter to test their blood glucose until replacement product from LifeScan arrives. If an alternate meter is not available, patients may continue to test using the recalled OneTouch SureStep Test Strips. However, if patients obtain results above 400 mg/dL, they should contact their healthcare professional for further instructions because their glucose may be significantly higher.