



DATE: February 26, 2010
TO: All Local Health Departments
Attn: Chief Food Inspection Officer
FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program
SUBJECT: LifeScan Recall

SUGGESTED ACTION: Unclassified Recall; OneTouch® SureStep® Test Strips because they may provide falsely low glucose results; Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the strips being recalled were distributed in the State of Indiana. 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. Detail information is not available at this time. In addition, if any recalled product is found, please notify this office at 317-233-7360.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

LifeScan Recalls Specific Lots of Consumer and Professional OneTouch® SureStep® Test Strips Due To Inaccurate Readings at High Levels

Contact:

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FOR IMMEDIATE RELEASE -- MILPITAS, Calif., Feb. 24 /PRNewswire/ -- LifeScan, Inc. is conducting a voluntary recall in the United States 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.

The eight lots of consumer OneTouch SureStep Test Strips being recalled are:

Recalled Lot	Size	Description
# 2969251	100-ct	OneTouch SureStep
# 2969798	100-ct	OneTouch SureStep
# 2982369	100-ct	OneTouch SureStep
# 2983467	100-ct	OneTouch SureStep
# 2969795	50-ct	OneTouch SureStep
# 2982566	50-ct	OneTouch SureStep
# 2969481	50-ct	Medicare/Mail Order
# 2998193	50-ct	Medicare/Mail Order

Lot #'s are located on the outer carton and test strip vial.

Patients with test strips from the recalled lots are asked to call LifeScan at 800 574-6139 between 5:00 am and 7:00 pm Pacific Time, seven days a week or visit www.SureStep.com to request replacement product. Replacement product will be shipped immediately and provided free of charge.

While waiting for replacement product to arrive, 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.

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.

No injuries associated with these recalled test strips have been reported. However, 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. Patients with high blood glucose may or may not have certain symptoms including increased thirst, frequent urination, headaches, difficulty with concentration, blurred vision and fatigue (weak, tired feeling). High blood glucose must be recognized and treated promptly to avoid serious complications, such as coma and death.

Hospitals, clinics and other multi-patient facilities using SureStep®Pro®, SureStep®Flexx® or OneTouch® SureStep® Hospital Systems have also been notified of this issue. All three of these systems use SureStep®Pro® Test Strips which also may provide inaccurately low test results when the blood glucose reading is greater than 400 mg/dL. LifeScan has advised these facilities of the appropriate actions to take in order to continue to use these SureStepPro Test Strips. However, healthcare facilities with access to alternative means of testing should consider temporarily discontinuing their use of their SureStep Systems until replacement test strips are available.

This field action is limited to eight lots of OneTouch SureStep Test Strips sold for consumer use in the U.S., and select SureStepPro Test Strips used in healthcare facilities. Similar recall actions are being taken in other countries where the affected product was distributed.

In 2006 LifeScan stopped selling OneTouch SureStep Meters in the U.S. but continued to provide test strips. Today, OneTouch SureStep Meter users represent a very small portion of LifeScan's total customer base. The vast majority of LifeScan's customers now use OneTouch® Ultra® Brand Meters, which use an entirely different technology.

LifeScan, Inc. is a leading maker of blood glucose monitoring systems for people with diabetes. For information about diabetes care and LifeScan products and services, visit www.OneTouchDiabetes.com¹.

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