



DATE: December 4, 2013

TO: All Local Health Departments
Attn: Chief, Food Inspection Officer

FROM: *A. Scott Gilliam*
A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: Abbott Recall [Medical Device]

AFFECTED PRODUCT: The affected test strips are from lots that hold expiration dates between May 2014 and March 2015, and can be identified as follows:

Lot Numbers				
1281732	1363321	1367917	1350414	1363015
1283345	1365056	1373262	1365921	1366006
1283603	1365920	1374907	1363109	1366337
1285007	1365934	1366515	1366347	1366111

SUMMARY: Unclassified Recall; Abbott today announced it is initiating a voluntary recall of 20 lots of FreeStyle® and FreeStyle Lite® Blood Glucose Test Strips in the United States. These lots of test strips may produce erroneously low blood glucose results when used with both "FreeStyle® Blood Glucose Meter" and "FreeStyle® Flash Blood Glucose Meter"

SUGGESTED ACTION: Please see the attached recall in the case of consumer inquiries.

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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.

Abbott Issues Voluntary Recall of Certain FreeStyle® and FreeStyle Lite® Blood Glucose Test Strips in the United States

Contact

Consumer:
1-888-736-9869

FOR IMMEDIATE RELEASE - November 27, 2013 - Abbott today announced it is initiating a voluntary recall of 20 lots of FreeStyle® and FreeStyle Lite® Blood Glucose Test Strips in the United States. These lots of test strips may produce erroneously low blood glucose results when used with both "FreeStyle® Blood Glucose Meter" and "FreeStyle® Flash Blood Glucose Meter" [neither of which have been in production since 2010], as well as the OmniPod® Insulin Management System.

When the test strips are used with the newer FreeStyle brand meters including FreeStyle® Freedom Blood Glucose Meter, FreeStyle Lite® Blood Glucose Meter* and FreeStyle Freedom® Lite Blood Glucose Meter*, the blood glucose test results are not affected. Testing with the FreeStyle InsuLinx® Blood Glucose Meter is not affected by this action, as FreeStyle InsuLinx Blood Glucose Meter uses FreeStyle InsuLinx test strips.

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The company is notifying healthcare professionals, pharmacies, distributors and customers about the recall; customers affected by this action are instructed to call Abbott's diabetes care customer service at 1-888-736-9869 for a replacement of the affected test strips at no charge.

For more information, please visit abbottdiabetescare.com.

About Abbott Diabetes Care

Abbott Diabetes Care, based in Alameda, Calif., is a leader in developing, manufacturing and marketing glucose monitoring systems designed to help people better manage their diabetes. Additional information about Abbott Diabetes Care may be found at www.abbottdiabetescare.com.

About Abbott

Abbott (NYSE: ABT) is a global healthcare company devoted to improving life through the development of products and technologies that span the breadth of healthcare. With a portfolio of leading, science-based offerings in diagnostics, medical devices, nutritionals and branded generic pharmaceuticals, Abbott serves people in more than 150 countries and employs approximately 70,000 people.

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