NATIONAL PBM COMMUNICATION · December 4, 2008

LIFESCAN Issues Voluntary Urgent Medical Device Recall of Two Lots of OneTouch® SureStep® Test Strips

- LIFESCAN announced that it has voluntarily recalled two specific lots of OneTouch® SureStep® Blood Glucose Test Strips.
- These two lots may contain test strips that produce inaccurate blood glucose readings (i.e., low or no blood glucose readings).
- This is a patient level recall.
- The following two lots of OneTouch® SureStep® Blood Glucose Test Strips are affected and being recalled:

Product Description	NDC	Lot Number
Surestep Test Strips 100/vL	53885005210	2802961
Surestep Test Strips 50/bx	53885035950	2802962

(Example only)

- Return all remaining product at the facility/CMOP level with the affected lot numbers to McKesson, NOT as instructed in the product recall documents.
- Determine whether the affected lot numbers (refer to lot numbers provided above) were dispensed to any patient(s) and if so, identify the patient(s) and contact the patient(s) to provide instructions on how to obtain a new supply of test strips and return the test strips being recalled. The attached VAMC data may be used as a guide (data may not include direct purchases/drop shipments). CMOP data will be provided separately by a CMOP representative to Pharmacy Chiefs.
- Contact patients who may have received the affected product by any appropriate method. A sample letter can be found at: http://vaww.national.cmop.va.gov/PBM/Other%20Documents%20and%20Resources/Recall%20Patient%20Letter%20Template.doc. This template can be altered according to site-specific needs.
- Report any adverse reactions experienced with the use of these products to the VA ADERS program.
- Refer to the attached manufacturer notifications for further details regarding this urgent product recall.

ACTIONS:

- ***Facility Director*** *(or physician designee): Forward this document to the Facility Chief of Staff (COS) and report completion of actions to the VISN Director.*
- ***Facility COS:*** *Forward this document to all appropriate providers who prescribe these devices (e.g.,* ***primary care providers, endocrinologists, and diabetes specialists****, including contract providers, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate. Report completion of actions to the Facility Director.*
- ***ACOS for R&D:*** *Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).*
- ***VISN Directors:*** *Within 10 business days of receipt (due 12/18/2008), communicate to PBM/VAMedSAFE that all actions have been completed via the Feedback tool: http://vaww.national.cmop.va.gov/PBM/visn_drug_recalls_alerts/default.aspx.*

LIFESCAN
a Johnson & Johnson company

LifeScan, Inc. 1000 Gibraltar Drive, Milpitas, CA 95035-6312
Tel: 408•263•9789 Fax: 408•946•6070 www.LifeScan.com

November 24, 2008

URGENT: MEDICAL DEVICE RECALL
Voluntary Removal of Two Lots of. OneTouch® SureStep® Test Strips

Dear Pharmacist:

At LifeScan, we hold our products to the highest standards of quality; constantly working to ensure they provide glucose results patients and healthcare professionals can rely on. For that reason, we're also committed to communicating with you when we learn of product that may not be performing to our expected standards.

This letter is to advise you that LifeScan is voluntarily removing two specific lots of OneTouch® SureStep® Blood Glucose Test Strips. We are recalling these two lots because we have learned that a very small number of vials in these lots may contain test strips that could produce inaccurately low or no blood glucose test results.

We have also informed the U.S. Food and Drug Administration of this action.

Identifying OneTouch SureStep Test Strips Subject To Recall

The following two lots of OneTouch SureStep Test Strips are subject to recall:

Affected Lot Number	Description
2802961	**100-count OneTouch SureStep Test Strips**
2802962	**50-count OneTouch SureStep Test Strips**

Note: Credit for return of test strips will only be provided to those customers who have OneTouch SureStep Test Strips from either of the two lots identified in this letter. No other OneTouch® Brand products are included in this field action.

How To Receive Credit for Recalled OneTouch SureStep Test Strips

1. Locate and sequester any inventory of OneTouch SureStep Test Strips from either of the two lot numbers identified in this letter. If you do not have any OneTouch SureStep Test Strip from the affected lots, then your test strips are not subject to this program and you can continue to sell them.

2. Return any OneTouch SureStep Test Strips subject to recall for a credit following the normal return procedures of your supplier. If you have any questions about this action, please call LifeScan at **1 800 951-7616**.

3. While LifeScan will be notifying patients directly, we also request your assistance in sharing this information with your customers who purchase OneTouch SureStep Test Strip. Please post the enclosed "OneTouch SureStep Test Strip Notice" in a prominent location in your pharmacy. Please instruct consumers to contact LifeScan Customer Service directly at **1 866 840-1758** for more information.

Your Complete Satisfaction is Our Top Priority

Please know that, at LifeScan, we continually strive to ensure that we provide you with product of the highest quality. We apologize for any inconvenience this issue may cause, and we thank you for your continued support of LifeScan.

Sincerely,

Glenn Johnson,
Vice President, Strategic Customer Group

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a Johnson & Johnson company

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November 24, 2008

URGENT: MEDICAL DEVICE RECALL
Voluntary Removal and Replacement Of Two Lots of LifeScan, Inc. OneTouch® SureStep® Test Strips

Dear Valued Customer:

At LifeScan, we hold our products to the highest standards of quality; constantly working to ensure they provide glucose results you can rely on. For that reason, we're also committed to communicating with you when we learn of product that may not be performing to our expected standards.

This letter is to let you know that LifeScan is voluntarily removing and offering to replace free of charge two specific lots of OneTouch® SureStep® Blood Glucose Test Strips. We are replacing these two lots because we have learned that a very small number of vials in these lots may contain test strips that could produce inaccurately low or no blood glucose test results.

We have also informed the U.S. Food and Drug Administration of this action.

How To Tell If Your OneTouch SureStep Test Strips Are Affected

Please compare the lot numbers of any OneTouch SureStep Test Strips in your possession with the two affected lot numbers listed below. The lot number appears on the outside of the test strip box and on the test strip vial label. If you do not have any test strips from either of these two lots, then your OneTouch SureStep Test Strips are not affected and no further action is required. You can continue to use them to test your blood glucose.

Affected Lot Number	Description
2802961	**100-count OneTouch SureStep Test Strips**
2802962	**50-count OneTouch SureStep Test Strips**

(Example only)

Note: Replacement test strips will only be provided to those customers who have OneTouch SureStep Test Strips from either of the two lots identified in this letter. No other OneTouch® Brand products are included in this replacement program.

How To Receive Replacement OneTouch SureStep Test Strips

If you have any OneTouch SureStep Test Strips from either of the two lot numbers identified in this letter, please stop using them immediately and call LifeScan at **1 (866) 840-1758.** Tell the customer service representative that you have test strips that need to be replaced. You should also tell the representative if you have other test strips available to test with while you wait for your replacement test strips. The LifeScan representative will tell you how to return your affected test strips and will arrange to have replacement test strips sent to you at no charge. While you wait for your replacement test strips to arrive, please do not use the OneTouch SureStep Test Strips with the lot numbers identified in this letter.

Your Complete Satisfaction is Our Top Priority

Please know that, at LifeScan, we continually strive to ensure that we provide you with product of the highest quality. We apologize for any inconvenience this issue may cause, and we thank you for your continued support of LifeScan.

Sincerely,

LifeScan Customer Service

HENRY SCHEIN®
Henry Schein, Inc. • 135 Duryea Road • Melville, NY 11747

December 2, 2008

Internal Distribution Letter-Manufacturer Letter Attached

URGENT: Product Recall (Consumer Level)

Manufacturing Firm:
Company LifeScan, Inc.

PRODUCT:

Product Code	Product Description	NDC	Lot Number
567-7245	Surestep Test Strips 100/vL	53885005210	2802961
567-9722	Surestep Test Strips 50/bx	53885035950	2802962
567-6882	Surestep BLD Glucose Test Strip 50/bx	53885035950	2802962

REASON:

The manufacturer of the above listed items has voluntarily issued this recall, specified lot numbers only, due to a very small number of vials in these lots which may contain test strips that could produce inaccurately low or no blood glucose test results.

LEVEL:

This recall is to the Consumer level.

CLASS:

This recall has not been classified. No additional notification will be given if this is classified as either a Class II or a Class III since the return information will be the same. The only update you will receive is if this is upgraded to a Class I.

ACTION:

Please examine your inventory to verify if you have any of the specified lots on hand. If so, immediately cease distribution/use of this product and remove it from your shelves. The product must be returned within 30 days, to the following address: **Henry Schein, Inc., 41 Weaver Road, Denver, PA 17517.** Please clearly mark the carton **Recall Material Enclosed**. Your account will be credited accordingly for product, shipping and handling.

Only returns of the above noted recalled lot numbers purchased from Henry Schein, Inc. will be credited to your account. In order to expedite your credit, please send a copy of your invoice if available.

OTHER INFORMATION:

If you have any questions regarding this matter, please contact LifeScan at 800-600-7226.

We apologize for any inconvenience and thank you for your immediate attention to this matter.

Sincerely,

Peter Schmidt
Recall Coordinator

HENRY SCHEIN®
Henry Schein, Inc. • 135 Duryea Road • Melville, NY 11747

December 2, 2008

Internal Distribution Letter-Manufacturer Letter Attached

URGENT: Product Recall (Consumer Level) Response Form

Please note that only product codes and lot numbers affected by this recall should be returned to Henry Schein, Inc. Accounts will not be credited for non-affected product codes or lot numbers returned.

PLEASE SHIP AFFECTED PRODUCT TO:	FORWARD RESPONSES ONLY TO:
Henry Schein, Inc. 41 Weaver Road Denver, PA 17517 **ATT: Customer Returns Department**	Regulatory Affairs Department (E-355) 135 Duryea Road Melville, NY 11747 **ATT: Regulatory-RR - Or - Fax Response To (631) 843-5557**

We have checked inventory and the following affected product has been found:

Product Code	Description	NDC	Lot Number	Quantity
567-7245	Surestep Test Strips 100/vL	53885005210	2802961	
567-9722	Surestep Test Strips 50/bx	53885035950	2802962	
567-6882	Surestep BLD Glucose Test Strip 50/bx	53885035950	2802962	

_____ **WE DO NOT HAVE ANY OF THE AFFECTED ITEMS.**

_____ _____ _____
Signature/Title Company Date

FOR HENRY SCHEIN, INC. INTERNAL USE ONLY		
TSM	**Lot Number (s)**	**Quantity**