NATIONAL PBM COMMUNICATION · November 29, 2013

Recall of Certain Lots of Abbott FreeStyle® Glucose Test Strips

- Abbott Diabetes Care recalled certain lots of FreeStyle® and FreeStyle Lite® Blood Glucose Test Strips due to producing out of range control solution results and erroneously low blood glucose results when using FreeStyle® Blood Glucose Meters, FreeStyle Flash® Blood Glucose Meters, and the FreeStyle® meter built into the Omnipod® System.
- A falsely low blood glucose level may lead to an insulin dosing error that could bring about a hyperglycemic episode requiring immediate medical attention.

PRODUCT SEQUESTERING ACTIONS

- Affected lot(s) include:

MATERIAL DESCRIPTION	ITEM	MANUFACTURER	LOT NUMBER	EXPIRATION	MANUFACTURER INITIAL SHIP
FREESTYLE TEST STRIP 50CT	10029511 444810	9907312050	1285007	06/30/2014	11/12/2012
FREESTYLE LITE TEST STRIP 100CT	10050025 771624	9907370827	1363015 1363109 1365921	11/30/2014 11/30/2014 12/31/2014	11/12/2012
FREESTYLE LITE TEST STRIP NFRS 50CT	10050032 771701	9907370819	1365056 1366347 1367917	11/30/2014 12/31/2014 12/31/2014	11/12/2012
FREESTYLE LITE TEST STRIP 50CT	10050035 771720	9907370822	1283345	05/31/2014	11/12/2012
FREESTYLE LITE TEST STRIP INST 50CT	10051542 799876	9907371026	1281732 1283603	05/31/2014 05/31/2014	11/12/2012
FREESTYLE STRIP DL PREPACK 4X50CT	10098735 129465	699073120502	1285007	06/30/2014	11/12/2012
FREESTYLE LITE DL STRIP PREPACK 4X50CT	10098736 129472	9907370822	1283345	05/31/2014	11/12/2012
FREESTYLE LITE STRIP PREPACK 4X100CT	10098737 129484	699073708274	1363015 1363109 1365921	11/30/2014 11/30/2014 12/31/2014	11/12/2012

- Following the action due dates in **Product Recall Office Log # 7592** (available at: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html), sequester and then return all remaining affected product at the CMOP/facility per manufacturer's instructions. Please inform your Facility Recall Coordinator when completed.

PATIENT NOTIFICATION ACTIONS

- Determine whether the affected product(s) was dispensed to any patient(s) for home administration. Consult with diabetic clinics and diabetic educators because they are typically well aware of patients on non-contracted meters and strips. CMOP data (if available) will be provided by a CMOP representative to Pharmacy Chiefs.
- If an affected lot(s) was dispensed to a patient(s) for home administration, then:
  - Identify the patient(s).
  - Contact patient(s) who may have received the affected product(s) for home administration by any appropriate method.
    - A sample letter can be found at:

https://vaww.cmopnational.va.gov/cmop/PBM/Other%20Documents%20and%20Resources/Recall%20Patient%20Letter%20Template.doc

- Provide patient(s) in possession of the recalled product with instructions on the following:
  - How to return the product being recalled to the pharmacy.
  - How to obtain a new supply of product.
  - When the correct product is received, patients should begin using the new product and return the recalled supply as instructed.
- Providers should continue to report any adverse reactions with the use of any glucose test strip(s) or glucose meter kit(s) by entering the information into CPRS' Allergies/ Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (1-800-FDA-1088, fax 1-800-FDA-0178, online at https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm, or by mail).

FEEDBACK NOTIFICATION ACTIONS:

- ***Facility Director*** *(or physician designee): Report completion of actions to the VISN Director.*
- ***Facility COS and Chief Nurse Executives:*** *Forward this document to all appropriate providers who prescribe this agent (e.g.,* ***primary care providers, endocrinology, and pharmacy staff, 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 issue (due 12/13/2013), communicate to PBM/VAMedSAFE that all product sequestration actions have been completed via the Feedback tool: https://vaww.cmopnational.va.gov/cmop/PBM/visn_drug_recalls_alerts/default.aspx .*