




Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: June 10, 2014

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

FROM: 
Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Diabetic Supply of Suncoast, Inc. – RECALL [Medical Device]

AFFECTED PRODUCT: BMB-BA006A Advocate Redi-Code+ blood glucose test strip lots manufactured by BroadMaster Bio-Tech Corp currently in the market place.

SUMMARY: Unclassified Recall; The recall is being conducted due to a labeling error which could result in confusion about which meter models the Redi-Code+ BMB-BA006A blood glucose test strips are designed to be used with. In the incorrect labeling, the test strips model (BMB-BA006A) was omitted.

This error may lead users to believe they can use the Advocate Redi-Code+ BMB-BA006A blood glucose test strips with the Advocate Redi-Code blood glucose meters, model numbers TD-3223E, TD-4223E, TD-4223F, TD-4276 manufactured by Taidoc Technology Corp. The Advocate Redi-Code+ BMB-BA006A blood glucose test strips should only be used with the Advocate Redi-Code+ BMB-EA001S and EA001A blood glucose meters manufactured by BroadMaster Bio-Tech Corp.

The recalled products were distributed nationwide.

SUGGESTED ACTION: For consumer inquiry only. Customers who have the affected test strips can contact Diabetic Supply of Suncoast, Inc. directly for further information to determine if the test strips are being used in the proper manor or if they need to be returned to Suncoast for replacement.

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.



2 North Meridian Street • Indianapolis, IN 46204
317.233.1325 tdd 317.233.5577
www.statehealth.in.gov

To promote and provide
essential public health services.

Diabetic Supply of Suncoast, Inc. issues a Nationwide Voluntary Recall of BMB-BA006A Advocate Redi-Code+ Blood Glucose Test Strips

Contact:

Consumer:
(561) 296-0488
sthuss@dsosi.com

FOR IMMEDIATE RELEASE - June 6, 2014 - Diabetic Supply of Suncoast, Inc. initiated a nationwide voluntary recall of all BMB-BA006A Advocate Redi-Code+ blood glucose test strip lots manufactured by BroadMaster Bio-Tech Corp currently in the market place. The Advocate Redi-Code+ BMB-BA006A blood glucose test strips are being recalled due to a labeling error which could result in confusion about which meter models the Redi-Code+ BMB-BA006A blood glucose test strips are designed to be used with. In the incorrect labeling, the test strips model (BMB-BA006A) was omitted.

This error may lead users to believe they can use the Advocate Redi-Code+ BMB-BA006A blood glucose test strips with the Advocate Redi-Code blood glucose meters, model numbers TD-3223E, TD-4223E, TD-4223F, TD-4276 manufactured by Taidoc Technology Corp. The Advocate Redi-Code+ BMB-BA006A blood glucose test strips should only be used with the Advocate Redi-Code+ BMB-EA001S and EA001A blood glucose meters manufactured by BroadMaster Bio-Tech Corp.

Suncoast is recalling the test strips in an effort to avoid confusion and the possible misuse of the Advocate Redi-Code+ blood glucose test strips with the Taidoc meters listed above, which could result in incorrect glucose results. Falsely high or falsely low glucose results could potentially cause missed or delayed hyperglycemia or hypoglycemia detection and lead to no treatment or inappropriate treatment. Delayed or inappropriate treatment of hyperglycemic or hypoglycemic states could lead to serious health consequences, including death.

Customers who have the affected test strips can contact Diabetic Supply of Suncoast, Inc. directly for further information to determine if the test strips are being used in the proper manor or if they need to be returned to Suncoast for replacement. Test strips will be replaced with relabeled boxes of test strips to avoid any chance of confusion. Consumers should stop using the above mentioned test strips and contact Suncoast to find out if this recall pertains to the test strips they have in their possession and if so how to have them replaced for the relabeled products manufactured by BroadMaster Bio-Tech. Customers who have the Advocate Redi-Code blood glucose meters manufactured by Taidoc Technology Corp should follow the product User Manual for information about the appropriate test strips to be used with the Taidoc meters.

Diabetic Supply of Suncoast, Inc. is notifying its wholesale Distributors, Pharmacies, Medical Supply stores, Health Care Providers and direct customers throughout the entire US and Virgin Islands by letter and Press Release about the specifics of the recall. Customers with questions may contact Diabetic Supply of Suncoast at (561) 296-0488 between the hours of 9:00AM and 5:00PM Monday through Friday Eastern standard time or view the information at www.dsosi.com.

Adverse reactions or quality problems experienced while using the above mentioned test strips may be reported to:

- Diabetic Supply of Suncoast, Inc. HC 3 PO Box 6630 Dorado, PR 00646 (561) 296-0488
www.dsosi.com

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm¹
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm² or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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Diabetic Supply of Suncoast, Inc. issues a Nationwide Voluntary Recall of BMB-BA006A Advocate Redi-Code+ Blood Glucose Test Strips
Photos



INCORRECT



CORRECT

