U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Diabetic Supply of Suncoast, Inc., Advocate Redi-Code+ BMB-BA006A Blood Glucose Test Strips – Labeling Error May Lead to Use of Incorrect Glucose Meters

Recall Class: Class I

Date Recall Initiated: June 6, 2014

Products: Advocate Redi-Code+ BMB-BA006A Blood Glucose Test Strips – All Lots

Distribution Dates: January, 2012 – June 6, 2014

Use: The Advocate Redi-Code+ BMB-BA006A Blood Glucose Test Strips are used at home by people with diabetes to monitor their blood glucose levels. Blood glucose test strips measure the amount of glucose (sugar) in a blood sample collected by pricking the skin.

Recalling Firm:
Diabetic Supply of Suncoast, Inc.
Barrio Espinosa Road #2 Km 26.2
Dorado, PR 00646

Manufacturer:
BroadMaster Bio-Tech Corp.
7f, No. 168-2, Liancheng
Zhonghe City, Taipei County, Taiwan 23553

Reason for Recall:
A labeling error omitting the test strips model number (BMB-BA006A) could lead to use of the Advocate Redi-Code+ BMB-BA006A blood glucose test strips manufactured by BroadMaster Bio-Tech Corp. with the incorrect glucose meters.

Suncoast is recalling the test strips to avoid confusion and possible misuse of the test strips with the Advocate Redi-Code blood glucose meters manufactured by Taidoc Technology Corp. Misuse could result in incorrect glucose test results.

Falsely high or falsely low glucose results could potentially cause missed or delayed high blood sugar (hyperglycemia) or low blood sugar (hypoglycemia) detection and lead to no treatment or inappropriate treatment.

Delayed or inappropriate treatment of high blood sugar or low blood sugar may lead to serious adverse health consequences, including death.

For more information (including pictures of the incorrect and correct labeling), see the firm's **press release (/Safety/Recalls/ucm400559.htm)**.

Public Contact: Customers may contact Diabetic Supply of Suncoast at (561) 296-0488 between 9:00 a.m. and 5:00 p.m., Monday through Friday, Eastern Time or view the information at **www.dsosi.com (http://www.dsosi.com/)** **(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**.

FDA District: Puerto Rico District Office

More Information about this Recall:
On June 6, 2014, Diabetic Supply of Suncoast, Inc. issued a Press Release and sent an Urgent Medical Device Voluntary Recall letter (with return receipt) announcing the recall to its wholesale distributors, pharmacies, medical supply stores, health care providers, and direct customers throughout the U.S. and Virgin Islands. The letter identified the product, the problem, and the actions to be taken.

Consumers:

- If you know you have the affected Advocate Redi-Code+ BMB-BA006A blood glucose test strips manufactured by BroadMaster Bio-Tech Corp., stop using them.
- Contact Suncoast if you are not sure whether or not the recalled test strips are in your possession and if so, how to replace them for the relabeled test strips manufactured by BroadMaster Bio-Tech.

Note: Consumers who have the Advocate Redi-Code blood glucose meters manufactured by Taidoc Technology Corporation should follow the product User Manual for information about the appropriate blood glucose test strips to be used with the Taidoc blood glucose meters. The Advocate Redi-Code blood glucose meters manufactured by Taidoc Technology Corporation are not subject to this recall.

Wholesale Distributors, Pharmacies, Medical Supply Stores, and Health Care Providers:

- Immediately examine your inventory and quarantine the recalled products.
- Contact Suncoast to determine if the Advocate Redi-Code+ BMB-BA006A blood glucose test strips in your possession are being used with the correct blood glucose meter or if they need to be returned to Suncoast for replacement.
- Suncoast will replace the affected test strips with relabeled boxes of test strips to avoid any chance of confusion.
- Notify your customers if you have further distributed these recalled products.
- Complete the form enclosed with the recall letter and return it to Suncoast, even if you don't have the affected products in your inventory.

About Class I Recalls
Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/)** either online, by regular mail or by FAX.