Food/Drug/Pet Recall: Sundial

To be in compliance with FDA Drug Regulations, Sundial is requesting an immediate recall, removal and return, of all Sundial Products, distributed from the period beginning January 1, 2014 through current, that have labeling containing/making drug claims stating the product(s) can diagnose, cure, mitigate, treat or prevent disease. The recalled drug products are misbranded and deemed unapproved drugs based on labeling claims which could result in a delay of appropriate treatment by a healthcare provider. Because these products are unapproved, their safety and efficacy have not been established. While specific risks to patients, from use of these adulterated products, cannot always be identified or assessed, it is also not possible to rule out patient risks resulting from the use of such products.

The products included for recall are:

Tenadam Herb Flax Seed Oil & Honey Blend Mitmitta (Cayenne Pepper)
Spiced Tea Bitter Kola (Arogbo) Mahogany Bark
Nigerian Moringa Leaf Powder Jamaican Bissy Powder Chaney Root
Jamaican Turmeric Ghanian Black Spice Cerasee Bay Leaves, Mango Bark
Bitter Wood Piss A Bed Asthma
Devil Horsewhip White Pond Lily Blood Pressure
Mango Leaf Purple Sage Heart
Red Water Grass Quassia Wood Worms and Parasites
Sarsaparilla Trumpet Leaf Flu-Allergies /HayFever
Marsh Marigold White Jointa Arthritis
Sea Moss/ Irish Moss White Sage Axum Traditional Ethiopian Honey Beverage
Dog Blood Guinea Hen Weed Black Sage
Guava Leaf Sundial Cassava Meal Black Wiss
Jack in the Bush Cocoa Balls Cinnamon
King of the Forest African Fever Bush Palo De Brazil
ETHIOPIAN ABISH (FENNUGREEK SEED PWD.) Mojo Bush Broom Weed
Ethiopian Traditional Talba (Flaxseed Meal Cereal) Blood Leaf Bread Nut
Fever Grass Wood & Root Tonic Jamaican and Tropical Raw Honey
Jamaican Milk Wiss Koromantee Hemp Seed Oil
Spanish Needle Ashanti Talibah’s Tooth Powder and Ethiopian Coffe
Fig Leaf African Manback Tonic Blue vervain
Diabetics Pimento

All products used as a Sundial Herbs can be identified by the "Sundial" label with brown glass bottles, boxes, Ziploc bags and paper bags with clear viewing windows. This was distributed state or nationwide via the Sundial Herb website (http://sundialherbs.com/sundial/), or any other website or store pick up at 3609 Boston Road, Bronx, New York. Please contact Sundial Herbs to schedule return orders for proper disposal and destruction of the products.
The Sundial Herb company is halting product distribution of all products on their website and in their store location. Sundial Herbs recommends stopping use of these recalled products. No illnesses have been reported to date. However, if consumers have problems that may be linked to Sundial Herbs they should contact a doctor immediately.

Your immediate action, and response, is required. For questions or assistance in carrying out the request, please call Sundial (718) 798-3962.

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
- Regular Mail or Fax: Download form 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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.