



Whole Food Supplements

November 15, 2001

2 4 0 2 '02 FEB 19 2 11 18



The Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. Street S.W.
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

1. *Tribulus terrestris* leaf and furostanol saponins, the ingredients in Tribulus Tablets, helps promote healthy male physiology.
2. In clinical trials this herb has been particularly useful for enhancing libido and sexual performance in men.
3. It may also help to restore or build vitality and assist in responding to stress.

These statements are made for a dietary supplement containing ~~Tribulus terrestris~~ herb extract, ~~steroidal saponins, furostanol glycosides (including protodioscin and protogracillin)~~, small quantities of spirostanol glycosides, sterols and other compounds. Other ingredients include calcium acid phosphate, cellulose, hypromellose, magnesium stearate, and sodium starch glycollate. The name of the product is Tribulus Tablets.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden
Standard Process Inc.

975 0162  LET 9217

79088