

VITAL NUTRIENTS

November 18, 2004

Office of Nutritional Products Labeling
and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Pkwy
College Park, MD 20740

NOV 21

Re: Notification for Statement on Dietary Supplement Labels

Dear Sir/Madam:

This notification is being submitted on behalf of Vital Nutrients, Middletown, Connecticut, a distributor of dietary supplement products.

Pursuant to the requirements of Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. § 343(r)(6), and in accordance with the authorized provisions of 21 CFR § 101.93(a), your Agency is hereby notified that Vital Nutrients has made statements of "nutritional support", as described in 21 U.S.C. § 343(r)(6)(A), for its dietary supplement(s) as follows:

[SEE ATTACHED LIST OF EACH SUPPLEMENT NAME AND
TEXT OF EACH STATEMENT BEING MADE]

As required, enclosed are two photocopies of this notification.

The undersigned certifies on behalf of Vital Nutrients that the information presented and contained in this correspondence is complete and accurate.

Sincerely yours,



Mitch Kennedy, ND
Consultant to Vital Nutrients
Mitch Kennedy, ND P.C.
85 Arch Rd.
Avon, CT 06001
(860) 673-9954
fax: (860) 673-4063
Drmitch@healwithnature.com

975 0162

LET 15056

VitalNutrients ♦ 860-638-3675 ♦ FAX 860-638-3651
50 Silver St., Middletown, CT 06457

STRUCTURE AND FUNCTION CLAIM

Slippery Elm

Slippery Elm has traditionally been used to support normal stomach function, soothe occasional stomach upset and heartburn, and maintain levels of gastric mucous that are already in the normal range.*

* These statements have not been evaluated by the Food & Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

STRUCTURE AND FUNCTION CLAIM

Berberine (200 mg capsules)

Berberine is derived from the plant *Berberis aristata*, and is supplied as an extract as berberine sulfate. Berberine has traditionally been used to support regular and normal bowel function in healthy individuals.*

*This statement has not been evaluated by the Food & Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.