DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

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FEB 28 2001

Ms. Karen Horbatt
President
The Green Turtle Bay Vitamin Co., Inc.
PO Box 642
56 High Street
Summit, New Jersey 07901

Dear Ms. Horbatt:

This is in response to your letters of January 20, 2001 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that The Green Turtle Bay Vitamin Co., Inc. is making the following claims, among others, for the products:

Primrose Oile [sic]

"...tonic for inflammatory conditions"
"...maintains healthy cholesterol levels"
"...maintains normal blood pressure"
"...support for infantile eczema, painful breats [sic], painful joints and nervous conditions"
"...beneficial effect on the course of diabetic neuropathy"

PowerSleep

"...effective for sleep disturbances resulting nervous condition"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, cure, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and

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that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

You also submitted a letter pursuant to 21 U.S.C. 343(r)(6) for the product **Signal369**. You stated that this product was the subject of a claim stating "Omega-3s are reported to lower fats in the blood and thus reduce the risk of coronary disease." This statement is a claim of a relationship between omega-3 fatty acids and coronary heart disease. This statement is not a claim subject to 21 U.S.C. 343(r)(6), but rather a health claim subject to 21 U.S.C. 343(r)(1)(B). Health claims for dietary supplements require premarket authorization by FDA. An unauthorized health claim on the label or in the labeling of a dietary supplement would misbrand the dietary supplement under 21 U.S.C. 343(r)(1)(B) and would cause the product to be a misbranded drug under 21 U.S.C. 352(f)(1) and an unapproved new drug under 21 U.S.C. 355(a).

In a letter dated October 31, 2000, FDA issued its decision in response to a court order directing the agency to reconsider the health claim "Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease" in dietary supplement labeling (*Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999)). In its letter, FDA explained that it had decided not to issue a regulation authorizing such a health claim without qualification because the evidence for the claim did not meet the scientific standard of validity by which the health claim regulations require the agency to evaluate proposed health claims. However, because the agency found that the evidence for the claim outweighed the evidence against it, the letter set forth conditions under which FDA intends to exercise enforcement discretion with respect to the use of a qualified health claim for omega-3 fatty acids and reduced risk of coronary heart disease (see http://vm.cfsan.fda.gov/~dms/ds-ltr11.html). A copy of the October 31 letter is enclosed. Further, FDA issued a letter on February 16, 2001, to correct an oversight in the October 31 with respect to the use of the qualified claim. A copy of the February 16 letter is enclosed, along with a copy of a recent Federal Register notice describing FDA's current enforcement strategy for dietary supplement health claims (65 FR 59855; October 6, 2000). If you follow the conditions outlined in the October 31 and February 16 letters and the Federal Register notice, it is likely that your product will not be the subject of enforcement action by FDA.

Please contact us if you require further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

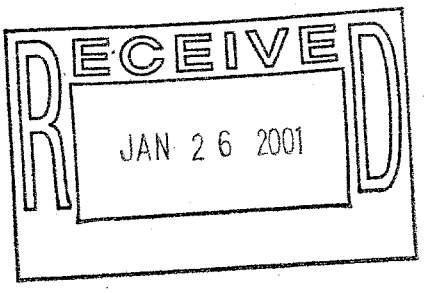
Enclosures

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, New Jersey District Compliance, HFR-MA340

cc:
HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (file, r/f)
HFS-810
HFD-310
HFD-314 (Aronson)
HFS-605
HFV-228 (Benz)
GCF-1 (Dorsey, Nickerson)
r/d:HFS-811:RMoore:2/16/01
Revised per GCF-1:LNickerson:2/22/01
f/t:HFS-811:rjm:2/22/01:docname:74200.adv:disc54

SECRETARY OF HEALTH AND HUMAN SERVICES
UNITED STATES OF AMERICA

NOTICE OF STATEMENTS UNDER 21 U.S.C. 403(r)(6)



To: Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration,
200 C St. SW., Washington, DC 20204

Date: January 20, 2001.

Re: This Notice covers the following Brand: Signal369.

PLEASE TAKE NOTICE under 21 U.S.C. 403(r) (6):

(i) The name and address of the manufacturer, packer, or distributor of the dietary supplement that bears the statement(s):

The Green Turtle Bay Vitamin Co., Inc.
PO Box 642, 56 High St.
Summit, NJ 07901

(ii) The text of the statement that is being made: see attached Exhibit A.

(iii) The name of the dietary ingredient or supplement that is the subject of the statement: see attached Exhibit A.

(iv) The name of the dietary supplement (including brand name), if not provided in response to paragraph (a)(2)(iii) on whose label, or in whose labeling, the statement appears: see attached Exhibit A.

CERTIFICATION

The undersigned, being duly authorized by the firm submitting the above Notice of Statements under 21 U.S.C. 403 (r) (6) certifies, as of the date first written above: (a) that the information contained in the Notice is complete and accurate, and (b) that the notifying firm has substantiation that the Statement(s) to which this Notice applies is truthful and not misleading.

The undersigned certifies that the above Certification is true and is aware that the undersigned is subject to punishment as for perjury if the Certification is willfully false. This Certification is made under 18 USC 1001which makes it a crime to submit false information to the Government.

Karen Horbatt

Karen Horbatt:
President:

NOTICE OF STATEMENTS UNDER 21 U.S.C. 403(r)(6)
Exhibit A

1. Brand Name(s) Included herein:

   Signal369

2. Dietary Ingredients or Supplements Included herein:

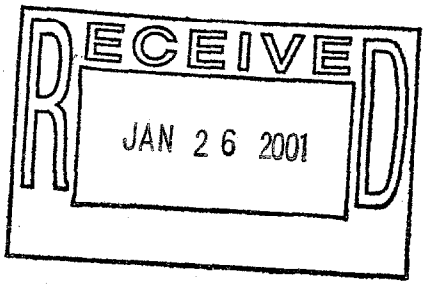
   (a) Omega-3 fish oils
   (b) Omega-3 and Omega-6

3. Statements Made with regard to each Ingredient (Same Order as #2):

   (a) Omega-3s are reported to lower fats in the blood and thus reduce the risk of coronary disease.
   (b) Omega-3 and Omega-6 improves brain activity.

SECRETARY OF HEALTH AND HUMAN SERVICES
UNITED STATES OF AMERICA

NOTICE OF STATEMENTS UNDER 21 U.S.C. 403(r)(6)



To: Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration,
200 C St. SW., Washington, DC 20204

Date: January 20, 2001.

Re: This Notice covers the following Brand: PowerSleep.

PLEASE TAKE NOTICE under 21 U.S.C. 403(r) (6):

(i) The name and address of the manufacturer, packer, or distributor of the dietary supplement that bears the statement(s):

The Green Turtle Bay Vitamin Co., Inc.
PO Box 642, 56 High St.
Summit, NJ 07901

(ii) The text of the statement that is being made: see attached Exhibit A.

(iii) The name of the dietary ingredient or supplement that is the subject of the statement: see attached Exhibit A.

(iv) The name of the dietary supplement (including brand name), if not provided in response to paragraph (a)(2)(iii) on whose label, or in whose labeling, the statement appears: see attached Exhibit A.

CERTIFICATION

The undersigned, being duly authorized by the firm submitting the above Notice of Statements under 21 U.S.C. 403 (r) (6) certifies, as of the date first written above: (a) that the information contained in the Notice is complete and accurate, and (b) that the notifying firm has substantiation that the Statement(s) to which this Notice applies is truthful and not misleading.

The undersigned certifies that the above Certification is true and is aware that the undersigned is subject to punishment as for perjury if the Certification is willfully false. This Certification is made under 18 USC 1001which makes it a crime to submit false information to the Government.

Karen Horbatt

Karen Horbatt:
President:

NOTICE OF STATEMENTS UNDER 21 U.S.C. 403(r)(6)
Exhibit A

1. Brand Name Included herein:

   PowerSleep

2. Dietary Ingredients or Supplements Included herein:

   (a) Passion Flower

   (b) Valerian Powder

   (c) L-glutamine

   (d) 5-hydroxy-tryptophan

3. Statements Made with regard to each Ingredient (Same Order as #2):

   (a) Passion Flower is used to support relaxation and sleep. An extract of Passion Flower relaxes motor nerves of the spinal cord.

   (b) Valerian is effective for sleep disturbances resulting from nervous condition.

   (c) L-glutamine is an amino acid believed to improve intelligence.

   (d) 5-HTP helps to normalize serotonin activity in the body

   (e) The ingredients (a) through (d) promote the production of serotonin.

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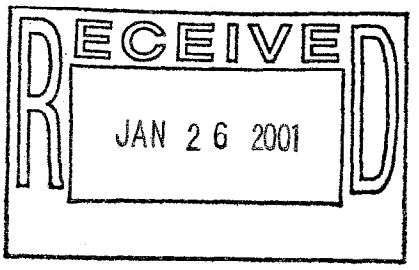

To: Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration,
200 C St. SW., Washington, DC 20204

Date: January 20, 2001.

Re: This Notice covers the following Brand: Primrose Oile.

PLEASE TAKE NOTICE under 21 U.S.C. 403(r) (6):

(i) The name and address of the manufacturer, packer, or distributor of the dietary supplement that bears the statement(s):

The Green Turtle Bay Vitamin Co., Inc.
PO Box 642, 56 High St.
Summit, NJ 07901

(ii) The text of the statement that is being made: see attached Exhibit A.

(iii) The name of the dietary ingredient or supplement that is the subject of the statement: see attached Exhibit A.

(iv) The name of the dietary supplement (including brand name), if not provided in response to paragraph (a)(2)(iii) on whose label, or in whose labeling, the statement appears: see attached Exhibit A.

CERTIFICATION

The undersigned, being duly authorized by the firm submitting the above Notice of Statements under 21 U.S.C. 403 (r) (6) certifies, as of the date first written above: (a) that the information contained in the Notice is complete and accurate, and (b) that the notifying firm has substantiation that the Statement(s) to which this Notice applies is truthful and not misleading.

The undersigned certifies that the above Certification is true and is aware that the undersigned is subject to punishment as for perjury if the Certification is willfully false.

This Certification is made under 18 USC 1001which makes it a crime to submit false information to the Government.

Karen Horbatt

Karen Horbatt:
President:

NOTICE OF STATEMENTS UNDER 21 U.S.C. 403(r)(6)
Exhibit A

1. Brand Name(s) Included herein:
   Primrose Oile

2. Dietary Ingredients or Supplements Included herein:

   (a) Evening Primrose oil

3. Statements Made with regard to each Ingredient (Same Order as #2):

(a) Evening Primrose oil supports liver and kidney functions

(b) Evening Primrose oil is used as a tonic for inflammatory conditions.

(c) Evening Primrose oil maintains healthy cholesterol levels.

(d) Evening Primrose oil relieves premenstrual tension.

(e) Evening Primrose oil maintains normal blood pressure.

(f) Evening Primrose oil is nutritional support for infantile eczema, painful breats, painful joints and nervous conditions.

(g) Evening Primrose oil has a beneficial effect on the course of diabetic neuropathy.