## SECRETARY OF HEALTH AND HUMAN SERVICES UNITED STATES OF AMERICA 0 9 4 6 01 MAR -8



## 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: Sunnie.

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.

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

Karen Horbatt:

President:

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

1. Brand Name Included herein:

Sunnie

- 2. Dietary Ingredients or Supplements Included herein:
  - (a) \_TMG, B6, folic acid and B12
- 3. Statements Made with regard to each Ingredient (Same Order as #2):
  - (a) TMG works along with B6, folic acid and B12 to augment the formation of SAMe