



OCT - 1 1999

R. Doug Metz, D.C.  
Sr. Vice President  
American Specialty Health & Wellness  
P.O. Box 509040  
San Diego, California 92 150-9040

Dear Dr. Metz:

This is in response to your letter of September 16, 1999 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 American Specialty Health & Wellness is making the following claim, among others, for the product **Vitamin B-Complex** : “During times of stress and infection, the body’s need for B-vitamins increases.”

**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 statement that you are making for this product suggests that it is intended for use to treat, prevent, mitigate, or cure disease, namely infections. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is 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-3 10, 7520 Standish Place, Rockville, Maryland 20855.

Your submission also states that you are making the following claim, among others, for the product **Folic Acid**: “...prevent neural tube birth defects in their babies.”

This statement is not a statement of nutritional support subject to 21 U.S.C. 343(r)(6), but is a health claim subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between folate and neural tube defects (see 21 CFR 101.79). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between folate and neural tube defects. A health claim for folate and neural tube defects on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.79 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, making a claim that is not in accordance with the requirements in 21 CFR 101.79 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, neural tube defects.

975-0163

LET 304

Your submission also states that you are marketing the product “**Melatonin**” as a dietary supplement. This product does not appear to meet the statutory definition of a dietary supplement contained in 21 U.S.C. 321(ff), and therefore, can not be marketed as a dietary supplement. We explain the basis for our opinion below.

The term “dietary supplement” is defined in 21 U.S.C. 321(ff). 21 U.S.C. 321(ff) provides that the term means a product (other than tobacco) intended to supplement the diet that bears or contains a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above ingredients. 21 U.S.C. 321(ff) further states that dietary supplements are intended for ingestion in a form described in 21 U.S.C. 350(c)(1)(B)(I) or in compliance with 21 U.S.C. 350(c)(1)(B)(ii), are not represented as conventional food or as a sole item of a meal or the dietary, and are labeled as a dietary supplement.

This product is not “intended for ingestion.” As stated above, the definition of dietary supplement in 21 U.S.C. 321(ff) states that a dietary supplement is a product “intended for ingestion.” The term “ingestion” has been addressed by the court in United States v. Ten Cartons, Ener-B Nasal Gel, 888 F. Supp. 381, 393-94 (E.D.N.Y.), aff’d, 72 F.3d 285 (2d Cir. 1995), which states:

The ordinary and plain meaning of the term “ingestion” means to take into the stomach and gastrointestinal tract by means of **enteral** administration. See Stedman’s Medical Dictionary (4th Lawyer’s Ed. 1976) (defining ingestion as the “introduction of food and drink into the stomach.”); Webster’s Third New International Dictionary (1976) (defining ingestion as “the taking of material (as food) into the digestive system.”)...

The interpretation of the term “ingestion” to mean **enteral** administration into the stomach and gastrointestinal tract is also supported by the language of the statutory sections immediately preceding and following section 350(c)(1)(B)(ii). Section 350(c)(1)(B)(I) states that the vitamin must be intended for ingestion in tablet, capsule or liquid form. Each of these forms denotes a method of ingestion that involves swallowing into the stomach. Section 350(c)(2) states that a food is intended for ingestion in liquid form under section 350(c)(1)(B)(I) “only if it is formulated in a fluid carrier and is intended for ingestion in daily quantities measured in drops or similar small units of measure.” This elaboration of “liquid form” also denotes ingestion by swallowing the fluid.

Therefore, because the term “ingestion” means introduced into the gastrointestinal tract, a product taken orally, but that delivers its contents only to the mouth or throat or that is absorbed directly from the mouth, is not subject to regulation as a dietary supplement because

Page 3 - Dr. R. Doug Metz

it is not "intended for ingestion." That your product is intended to deliver its contents prior to introduction into the gastrointestinal tract to exert its effect is evidenced by statements you are making that the "product is a sublingual lozenge (to be placed under the tongue) for rapid absorption."

Please contact us if we may be of further assistance.

Sincerely,

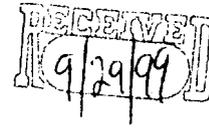
Lynn A. Larsen, Ph.D.  
Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

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, Los Angeles District Office, Office of Compliance, HFR-PA240

cc:

HFA-224 (w/incoming)  
HFA-305 (docket 97S-0163)  
HFS-22 (CCO)  
HFS-456 (file, r/f)  
HFS-450 (r/f, file)  
HFD-3 10 (BWilliams)  
HFD-3 14 (Aronson)  
HFS-605 (Bowers)  
HFV-228 (Betz)  
GCF- 1 (Dorsey, Barnett, Nickerson)  
f/t:HFS-456:rjm:9/30/99:docname:67387.adv:disc41



Office of Special Nutritionals  
HFS-450  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 c St. SW  
Washington DC 20204

Statement of Nutritional Support – MELATONIN

Pursuant to 21 CFR Part 101.93, American Specialty Health and Wellness (ASHW) files the following Statement of Nutritional Support for the Dietary Supplement marketed as MELATONIN

1) Name and Address of Distributor: ASHW 8989 Rio San Diego Drive, Suite 250, San Diego, CA 92108.

2) Text of Nutritional Support Statement being made:  
“Melatonin is a hormone that is showing promise in supporting several systems of the body. Recent scientific research is investigating melatonin’s usefulness in normal sleep and supporting a healthy immune system. This product is a sublingual lozenge (to be placed under the tongue) for rapid absorption.”

3) Name of dietary ingredient: See attached product label.

4) Brand Name: MELATONIN

5) Substantiation information on file at the company office. The corporate officer who can certify same is Dr. Doug Metz, Sr. Vice President.

Yours truly,

A handwritten signature in black ink, appearing to read "Doug Metz".

Dr. Doug Metz  
Sr. Vice President

67387



**Storage:** Keep tightly closed in a cool, dry place.

**Caution/Warning:** As with any supplement, herb or medication, do not use it while pregnant or lactating, or provide it to a child without consulting a physician. **Do not drive or operate heavy equipment** while taking this product. Do not give to children under 18 years of age. **Melatonin** lozenges are intended for periodic use only. Do not use consecutively for longer than 7 days. If you suffer from sleep disorders, cancer or immune disorders, do not use this product without first consulting your physician.

**Note:** This product is regulated by the FDA as a dietary supplement. If you have any questions about how you feel while taking this supplement, contact your physician. If you are taking any medication, have any disease or illness, consult your physician before taking this product. Do not stop or change prescribed medication without the permission or prescription of your physician.

DISTRIBUTED BY AMERICAN SPECIALTY™ HEALTH & WELLNESS,  
PO BOX 509040, SAN DIEGO, CA 92150-9040

Item # 40153

[www.buyhealthv.com](http://www.buyhealthv.com)

# MELATONIN

DIETARY SUPPLEMENT



100 LOZENGES

Premium Products for Your Health & Wellness

## Supplement Facts

Serving Size: 1 Lozenge  
Servings Per Container: 100

	Amount Per Serving	% Daily Value
Melatonin	500 mcg.	*

\*Daily Value not established.

Other Ingredients: Sorbitol, Magnesium stearate, Passion fruit flavor.

This product contains no yeast, milk, lactose, wheat, sugar, soy, or corn.

Directions For Use: Adults place 1 lozenge under tongue and allow to dissolve. For best results take just before bedtime. When traveling, lozenges may be taken at the expected bedtime in the new time zone. Continue for several days after arrival and upon return home.

1000 R/M

Double safety sealed with a printed outer shrink-wrap film and a printed inner bottle freshness seal. Do not use if either seal is broken or missing.



Office of Special Nutritionals  
HFS-450  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 c St. SW  
Washington DC 20204

9/29/99

Statement of Nutritional Support – VITAMIN B-COMPLEX

Pursuant to 21 CFR Part 101.93, American Specialty Health and Wellness (ASHW) files the following Statement of Nutritional Support for the Dietary Supplement marketed as VITAMIN B-COMPLEX

1) Name and Address of Distributor: ASHW 8989 Rio San Diego Drive, Suite 250, San Diego, CA 92 108.

2) Text of Nutritional Support Statement being made:

“The B-complex vitamins are water soluble and not stored in the body, so they must be replenished regularly. It is helpful to take the B vitamins as a complex because the function and absorption of one B vitamin partly depends on the availability of the others. Besides supporting the metabolism of carbohydrates, proteins and fats, B-complex vitamins support healthy growth and development of all tissues in the body. During times of stress and infection, the body’s need for B-vitamins increases. Intake of alcohol and caffeine also creates a greater need for vitamin B complex supplementation.”

3) Name of dietary ingredient: See attached product label.

4) Brand Name: VITAMIN B-COMPLEX

5) Substantiation information on file at the company office. The corporate officer who can certify same is Dr. Doug Metz, Sr. Vice President.

Yours truly,

A handwritten signature in black ink, appearing to read "Doug Metz".

Dr. Doug Metz  
Sr. Vice President

67387



This product contains no yeast, milk, lactose, wheat, sugar, soy, corn, artificial ingredients or preservatives.

**Directions For Use:** Take 1 capsule daily with a meal or water.

**Storage:** Keep tightly closed in a cool, dry place.

**Caution/Warning:** As with any supplement, herb or medication, do not use while pregnant or lactating, or provide it to a child without consulting a physician.

**Note:** This product is regulated by the FDA as a dietary supplement. If you have any questions about how you feel while taking this supplement, contact your physician. If you are taking any medication, have any disease or illness, consult your physician before taking this product. Do not stop or change prescribed medication without the permission or prescription of your physician.

DISTRIBUTED BY AMERICAN SPECIALTY™ HEALTH & WELLNESS,  
PO BOX 509040, SAN DIEGO, CA 92150-9040

[www.buyhealthy.com](http://www.buyhealthy.com)

1999 R/O

Item # 40158

# VITAMIN B-COMPLEX

DIETARY SUPPLEMENT



100 CAPSULES

Premium Products for Your Health & Wellness

## Supplement Facts

Serving Size: 1 Capsule

Servings Per Container: 100

	Amount Per Serving:	%Daily Value
Thiamin (as thiamin HCl)	100 mg	6667%
Riboflavin (as riboflavin / riboflavin 5-phosphate)	100 mg	5882%
Niacin (as niacinamide)	100 mg	500%
Vitamin B-6 (as pyridoxine HCl / pyridoxal 5-phosphate)	100 mg	5000%
Folic Acid	400 mcg	100%
Vitamin B-12 (cyanocobalamin tritrate)	100 mcg	1657%
Biotin (as biotin tritrate)	100 mcg	333%
Pantothenic k d (as d-calcium pantothenate)	100 mg	100%
Inositol	100 mg	
Choline (as choline bitartrate)	25 mg	

\*Daily Value not established.

Other Ingredients: Gelatin, Cellulose, Magnesium stearate.

Double safety sealed with a printed outer shrink-wrap film and a printed inner bottle freshness seal. Do not use if either seal is broken or missing.



Office of Special Nutritionals  
HFS-450  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 c St. SW  
Washington DC 20204

9/24/99

Statement of Nutritional Support – FOLIC ACID

Pursuant to 21 CFR Part 101.93, American Specialty Health and Wellness (ASHW) files the following Statement of Nutritional Support for the Dietary Supplement marketed as FOLIC ACID

- 1) Name and Address of Distributor: ASHW 8989 Rio San Diego Drive, Suite 250, San Diego, CA 92 108.
- 2) Text of Nutritional Support Statement being made:  
"Folic acid helps the body make DNA and RNA, two molecules which are the basis for cellular reproduction. For women of child bearing age consumption of 400 mcg. of folic acid will prevent neural tube birth defects in their babies. Folic acid also helps support healthy blood cell production."
- 3) Name of dietary ingredient: See attached product label.
- 4) Brand Name: FOLIC ACID
- 5) Substantiation information on file at the company office. The corporate officer who can certify same is Dr. Doug Metz, Sr. Vice President.

Yours truly,

A handwritten signature in black ink, appearing to read "Doug Metz".

Dr. Doug Metz  
Sr. Vice President

67387



Directions For **Use:** Take **1** capsule daily with meal **or** water.

Storage: Keep tightly closed in a **cool**, dry place

Caution/Warning As **with** any supplement, herb or medication, do not use it **while** pregnant or lactating, or provide it to a **child** without consulting a physician. Long term **mega-doses** may cause formation of folacin crystals in the kidney

Note: This product is regulated by the FDA as a dietary supplement. If you have any questions about how you feel while **taking** this supplement, contact your physician. If you are taking any medication, have any disease or illness, consult your physician before taking this product. Do not stop or change prescribed medication without the permission or prescription of your physician.

DISTRIBUTED BY AMERICAN SPECIALTY™ HEALTH & WELLNESS,  
PO BOX 509040, SAN DIEGO, CA 92150-9040

[www.buyhealthy.com](http://www.buyhealthy.com)

1999 R/O

Item 140160

# FOLKACID

DIETARY SUPPLEMENT



100 CAPSULES

Premium Products for Your *Health & Wellness*

## Supplement Facts

Serving Size: 1 Capsule

Servings Per Container: 100

	Amount Per Serving:	%Daily Value
Folic Acid	800 mg.	200%

Other Ingredients: Cellulose, Millet, Maltodextrin, Gelatin, Magnesium stearate

This product contains no yeast, milk, lactose, wheat, sugar, soy, artificial ingredients or preservatives.

Double safety sealed with a printed outer shrink-wrap film and a printed inner bottle freshness seal. Do not use if either seal is broken or missing.