Mannatech INCORPORATED



March 23, 2001

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

Re: Statement of Nutritional Support Notification

Dear Sir or Madam:

In accordance with 21 U.S.C. § 343 (r) and 21 CFR § 101.93, Mannatech Incorporated, 600 S. Royal Lane, Ste 200, Coppell, TX 75019, hereby submits an original and two copies of it's notification within 30 days of first marketing its product with the statements presented below:

Supplement Brand Name: Glyco•Bears™

Supplement Ingredients: See attached label.

Text of Statement of Nutritional Support: See attached brochure.

Mannatech Incorporated certifies that it possesses adequate substantiation for these statements of nutritional support; that the substantiation renders them truthful and non-misleading and thus permissible under the Dietary Supplement Health and Education Act (DSHEA); and that the information contained in this notice is complete and accurate.

Yours truly,

Dennis R. Sparkman, Ph.D.

Regulatory Affairs/R& D

Enclosures:

Glyco•Bears™ Brochure

Glyco•Bears™ Label

GlycoBears Label.Rev1 2/13/01 9:35 AM Paga 1



RECOMMENDED USE:

Children 4 years and older

take one tablet twice daily.

Children under age 4

take one tablet dally (see warning).

WARNING:

Do not give to children under age 4 unless supervised by an adult due to the risk of choking.

Store in a cool. dry place,

Product Number 124

Manufacturedfor: Mannatech hc.. Coppell TX 750 I9 USA www.mannatech.com

Mannatech[™] is a trademark of Mannatech h.c. Ambrotose[®]b aregistered trademark of Mannatech inc. Manapol[®]b aregistered trademark of Carrington Labs., Inc.

U.03129,0201.001



26 COMPLETE VITAMINS AND MINERALS

- Everything a growing body needs to support the typical diet.
- Made with 30 fruits and vegetables for better absorption.
- * Age-specific dosage.
- · No artificial colors. sweeteners or flavors.
- No sucrose or dextrose.

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

4	
4	
/ 6	
4	
4	
74	
/ 9	
/6 /6 /6 /6 /6 /6	
4	
%	
•	
4	
%	
%	
%	
%	
7b ov	
4	
% % % % %	-

% Daily Yalues Children < 4 years*

Calories	5		
Cholesterol	5 mg	f	1 %
lotal Carbohydrates	12	•	1%
nåsu.	lg	t	t
		ť	ı
Vitamin A (as retinyl palmitate, beta carotene			
and Dunaliella salina extract [alpha carotene			
cryptoxanthin zeaxanthin leutin) i n PNC*)	1.300 IU	100%	30%
Vitamin C (as ascorbic a d , sodium ascorbate			
and acerola cherry in PNC')	30 mg	75%	50%
Vitamin D (25 cholecalciferol in PNC)	200 NJ	50%	50%
Vitamin E as d-aipha-tocopherol succinate			
and mixed d-alpha-, d-beta-, d-delta-,			
and d-gamma-tocopherols in PNC)	15 N J	150%	50%
Thiamine (as thiamine mononitrate i n PNC)	0.75 mg	107%	50%
Riboflavin	0.85 mg	106%	50%
Niacin (as niacinamide in PNC')	10 mg	1117	50%
	(C) I mg	143%	50%
folate (as folic acid i n PNC')	200 mcg	100%	<u> </u>
Vitamin B ₁₇ (as cyanocobalamin in P N C)	3 mcg	100%	50%
Biotin	ISO mcg	100%	50%
Pantothenic acid (a d-calcium			74/1
pantothenate i n PNC')	5 mg	100%	50%
Calcium (a s calcium carbonate a d	<i>5</i> , 111 <u>F</u>	10074	J U N
calcium citrate i n PNC)	12.5 mg	2%	2%
lodine (as potassium iodide and kelp in PNC'	14.5 1112	4/1	6/1
[Ascophyllum nodosum - whole plant])	37.5 mg	53%	25%
Magnesium (as magnesium glycinate in PNC')	2 mg	1%	4 %
Zinc (as zinc citrate i n PHC)	3.75 mg	41%	23%
Selenium (as selenomethionine in PNC)	17.5 mg	4 1 70	13%
Copper (as cupric oxide and copper glycinate)	0.5 mg	50%	13%
Manganese (as manganese citrate i n PHC)	0.5 mg	+	13%
Chromium (as chromium niacinate diglycinate)	30 mcg	†	13%
Molybdenum (as sodium molybdak in PNC)	10 mg		25%
Potassium (a potassium citrate in PNC')	_		
Tourname (a pourmain course in PAC)	2 mg	t	<1%
Choline (as choline bitartrate i n PNC')	l mg		
Inositol	l mg		
PABA (p-aminobenzoic acid in PNC)	200 mcg	+	
Yanadium (a t vanadium glycinate)	10 mcg		
Biolayonoids	10 mcg	 ∤	
Ambrotose® complex (patent penaling)	12.5 mg		
Naturally occurring plant polysaccharides included	ina ing		
freeze-dried aloe vera gel extract - Hanapol*	neg Navder		
"Phytonutrient Complex (PNC)	25 mg	5 <u>1</u>	
Pineapple, broccoli, carrot, apple, orange, ton	nato estiluire	e houseals and	us has
blueberry, celery, grape, grapefruit, kale. plui	n minhami	inach steur	AL, DEEL,
watermelon, radish, lemon, lime, cantaloupe,	n, raspoers j, sp	under, strawed	iij.
peach pear. Zinger and green pea.	urerry, reek or	Jenom bebbet	autou' babai
peach pear. Zinger and green pea.			

Supplement Facts Serving Size | Tablet

* Percent Daily Yalues are based on a 2,000 calorie diet. † Daily Yalues not established.

Other ingredients: Sorbitol, stearic acid, fructo-oligosaccharides, natural flavors (Berry Burst only), dibasic calcium phosphate, turmeric (Iropical Ling only), natural flavors (Iropical Ling only), citric acid, magnesium stearate, malic acid (Berry Burst only), salicon dioxide, rice syrup solids and carmine (Berry Burst only).

WWW.KIES.MANNATECH.COM Introducing Glyco*Bears" Better Solutions to Global Heal MPMU.03136.0201 Glyco.Bears The Best Choice. Leading Brands: VES No Ne VES No No VES No No ·lintstones® GLYCO-BEARS" 26 Glycinated whole food matrix* (Fructooligosaccharides) Children's taste *Applies to magnesium, copper, chromium, and vanadium litamins & Minerals **Phytonutrient** Ambrotose[®] complex complex choice



Are They Getting Their Bear Essentials?

Do your kids get all the nutrition they need every day? If you're not sure, make sure they start today. Glyco Bears " give kids the bear necessities they need!

Glyco-Bears 'are great-tasting, chewable multivitamins formulated especially for children. Kids typically get lots of pizza, fast food and candy, but never enough fruit or vegetables during their key growth years. These sucrose- and dextrose-free treats contain 26 essential vitamins, minerals and other vital nutrients, in a base made from 30 different fruits and vegetables. Growing bodies thrive on the wholesome, delicious nutritional value of Glyco-Bears.

Glyco Bears" provide complete immune system and antioxidant support, plus renowned Ambrotose complex. Over-the-counter children's vitamins cannot compare to Glyco Bears, in nutritional value. Glyco Bears, contain no artificial colors flavors, sweeteners, iron, yeast or hydrogenated oils.

Kid-tested and kid-approved, Glyco-Bears" are the first children's multivitamins good enough to bear the Mannatech name. What Makes Glyco•Bears™ Better Than Other Kids' Vitamin Supplements?

• 26 vitamins and minerals in a real-food matrix for better absorption. Among these are:

Selenium, vitamins A, C and E, alpha carotene, beta carotene and lutein to help support the immune system.

Calcium, magnesium, manganese, vitamin D3 and zinc for strong, healthy bones and teeth.

BI, B6, B12 (thiamine), folic acid, chromium and vanadium-all of which contribute significantly to-overall good health.

- Ambrotose® complex- a glyconutrient which assists the body with immune support through cell-tocell communication.
- A phytonutrient complex made from 30 different fruits and vegetables, including:

Apple, Beet, Blueberry, Broccoli, Brussels Sprouts, Cantaloupe, Carrot, Cauliflower, Celery, Cherry, Grape, Grapefruit, Kale, Leek, Lemon, Lime, Onion, Orange, Papaya, Peach, Pear, Pineapple, Plum, Radish, Raspberry, Spinach, Strawberry, Tomato, Watermelon, Yellow Pepper

- Sucrose- and dextrose-free and does not contain any other ingredient that would contribute to hyperactivity, also helping children maintain the balanced blood sugar levels vital to many aspects of good health.
- Developed to support your child's health even through the teenage years.

Here are some perceptive Comments about Glyco Bears, obtained from the most demanding experts we could find:



These statements have not been evaluated by the Fnod and Drug.
Administration.

This product is not intended to diagnose, freat, cure or prevent any disease.