

Docket No. FDA-2021-P-0523  
Docket No. FDA-2021-P-0938

**BEFORE**

**THE UNITED STATES OF AMERICA**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**FOOD AND DRUG ADMINISTRATION**

**COMMENTS OF THE**

**AMERICAN HERBAL PRODUCTS ASSOCIATION**

**ON**

**TENTATIVE RESPONSES TO**  
**CITIZEN PETITIONS regarding THE REGULATORY STATUS OF**  
**N-ACETYLCYSTEINE**

**January 25, 2022**

## Prefatory remarks

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA members include domestic and foreign companies doing business as growers, importers, processors, manufacturers, and marketers of herbs and herbal products. AHPA serves its members by promoting the responsible commerce of products that contain herbs, including conventional human foods, dietary supplements, health and beauty products, animal products, and other products.

On June 1, 2021, the Council for Responsible Nutrition (CRN) submitted a citizen petition (FDA Dkt. No. FDA-2021-P-0523) requesting that the U.S. Food and Drug Administration (FDA) reverse its position that products consisting of or containing N-acetylcysteine (NAC)<sup>1</sup> do not meet the definition of “dietary supplement” under the Federal Food, Drug, and Cosmetic Act (FDCA).

On August 18, 2021, the Natural Products Association (NPA) submitted a citizen petition (FDA Dkt. No. FDA–2021–P–0938) requesting that FDA either determine that NAC is not excluded from the definition of “dietary supplement” under 21 U.S.C. § 321(ff)(3)(B) or, in the alternative, recommend and support the issuance of a regulation finding that NAC would be lawful for use in and as dietary supplements under the FDCA.

On October 8, 2021, AHPA submitted separate comments to each of the above-cited dockets to provide information in support of each of these citizen petitions.<sup>2</sup> Both of AHPA’s October 8, 2021, comment submissions are incorporated in their entirety by reference herein.

On November 24, 2021, FDA published tentative responses to both citizen petitions.<sup>3</sup> In these tentative responses, FDA stated that it is “open to receiving information from

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<sup>1</sup> NAC is also referred to as N-acetyl-L-cysteine or acetylcysteine.

<sup>2</sup> Comments of the American Herbal Products Association on the citizen petition of the Council for Responsible Nutrition regarding the regulatory status of N-acetylcysteine (Dkt. No. FDA-2021-P-0523) (Oct. 8, 2021), and Comments of the American Herbal Products Association on the citizen petition of the Natural Products Association regarding the regulatory status of N-acetylcysteine (Dkt. No. FDA-2021-P-0938) (Oct. 8, 2021).

<sup>3</sup> FDA tentative response to the citizen petition of the Council for Responsible Nutrition regarding the regulatory status of N-acetylcysteine (Dkt. No. FDA-2021-P-0523) (Nov. 24, 2021) and FDA tentative

interested parties on the earliest date that NAC was marketed as a dietary supplement or as a food” and also requested certain additional information.

The comments submitted here are limited to providing information on the marketing of conventional food and dietary supplement NAC products in the United States prior to October 15, 1994. The absence of comments responsive to the other topics identified in FDA’s tentative responses should not be taken to mean that AHPA agrees that such topics have any relevance to appropriate and lawful replies to the CRN and NPA citizen petitions.

### **NAC was marketed as an ingredient for use in conventional foods or dietary supplements prior to October 1994**

AHPA is aware of and is providing records here of marketing of NAC by ingredient suppliers as early as 1991. These include:

- Pharmline Inc. (Florida, NY) in a sales brochure dated August 1991 identified its product line of “fine nutritional products” to include “N Acetyl-L-Cysteine” under “Amino Acids/Derivatives” (relevant pages attached as Att. A, redacted).
- Island Organics Inc. (Dunellen, NJ) in a catalog provided to a potential U.S. buyer on May 2, 1994, included “N-Acetyl Cysteine” under “Vitamins and Nutritional Supplements” (relevant pages attached as Att. B, redacted).

The statutory definition of “dietary supplement” did not exist until October 1994. It is nonetheless obvious that both of the above examples, by use of the terms “nutritional products” and “Amino Acids/Derivatives” (in Att. A) and “Vitamins and Nutritional Supplements” (in Att. B), record marketing of NAC as an ingredient for use in conventional foods or products that the FDCA would classify as “dietary supplements” when the Dietary Supplement Health and Education Act (DSHEA) amended the FDCA by, among other details, adding a statutory definition for the “dietary supplement” class of goods at 21 U.S.C. § 321(ff) (FDCA § 201(ff)).

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response to the citizen petition of the Natural Products Association regarding the regulatory status of N-acetylcysteine (Dkt. No. FDA-2021-P-0938) (Nov. 24, 2021).

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## **NAC was marketed prior to October 1994 in dietary supplements**

AHPA is aware of and is providing records here of marketing of finished products in capsule form that contained NAC as an ingredient as early as 1991. These include:

- At least as early as May 1993 (and likely as early as November 1991 according to U.S. Patent and Trademark Office records<sup>4</sup>), Makers of KAL (Woodland Hills, CA) marketed a product identified by the brand “CELL DEFENSE” and recorded by FDA as containing NAC, as shown in the agency’s May 1993 report entitled “Enforcement Report: Statement of the enforcement priorities and practices of the Food and Drug Administration under section 409 of the Federal Food, Drug, and Cosmetic Act with respect to dietary supplements of vitamins, minerals, herbs, and other similar substances.” See page 3 of the cited report, in which FDA identified the products in referencing the “labeling of **dietary supplements** containing complex mixtures of ingredients” (emphasis added).
- As early as September 1993, NOW Foods Inc. (Glendale Heights, IL) marketed a product identified as “NAC N-acetyl cysteine with supporting nutrients, 100 capsules” and consisting of 600 mg NAC and other ingredients, as shown in a sell sheet distributed in September 1993 (relevant pages attached as Att. C). The contemporaneous marketing of other products containing or consisting of NAC can be inferred from the following statement on the sell sheet: “Compare our 600 mg with smaller size or lower potency competitors.”
- As early as January 1994, NF Formulas Inc. (Wilsonville, OR) marketed a product identified under the heading “Amino Acid Formulas” as “N.A.C.” and described as “600 mg N-Acetyl-L-Cysteine” in a 60 capsules size, as shown in a price list and catalog supplement published January 15, 1994 (relevant pages attached as Att. D, redacted).
- As early as May 1994, Country Life Inc. (Hayward, CA) marketed a product identified as “N-acetyl-cysteine” capsules, 750 mg, as shown in a certificate of analysis and bulk label provided in May 1994 by contract manufacturer VitaTech International Inc. (Tustin, CA) (attached as Att. E).

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<sup>4</sup> U.S. Trademark registration number 1,772,186 (serial number 74-210,351), in which the applicant identified the date of first use as November 1, 1991.

The statutory definition of “dietary supplement” did not exist until October 1994. It is nonetheless obvious that each of the above examples record marketing of products that the FDCA would classify as “dietary supplements” when DSHEA amended the FDCA by, among other details, adding a statutory definition for the “dietary supplement” class of goods at 21 U.S.C. § 321(ff) (FDCA § 201(ff)).

### **NAC was marketed prior to October 1994 as a conventional food**

AHPA is aware of and is providing a record here of marketing of a conventional food that contained NAC prior to October 15, 1994.

At least as early as 1993, Nature’s Plus (Melville, NY, and Long Beach, CA) marketed a product identified as a “beverage” under the brand “Oxy-Nectar” and containing “NAC (N-acetyl-cysteine)” as an ingredient, as shown on page 151 in the company’s 1993 product catalog (Att. F).

### **Summary**

AHPA greatly appreciates the opportunity to present comments on the regulatory status of NAC. AHPA staff and counsel will make themselves available at any mutually convenient time to further address any of the topics addressed herein. Please feel free to contact us if clarification or additional discussion is needed on the issues raised in these comments.

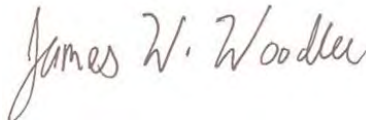
Respectfully submitted,



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PHARMLINE, Inc.

# The Source

- For Fine Nutritional Products -

August 1991

has over twelve years of experience serving the nutritional food and pharmaceutical industries. Pharmline, now in its fifth year, has established a track record of providing product, delivery and technical support to its customers. Our extensive contacts with manufacturers and suppliers in Europe, Asia and South America allow us to introduce cutting edge products to the industry.

Pharmline is a member of the Herb Research Foundation, the Institute of Food Technologists, the American Association of Candy Technologists, the NNFA, the Council for Responsible Nutrition and the American Herb Products Association.

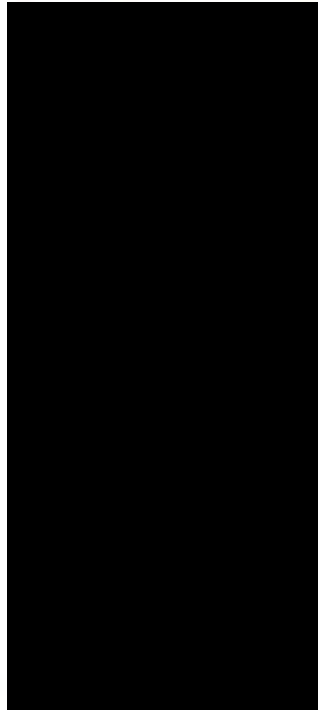
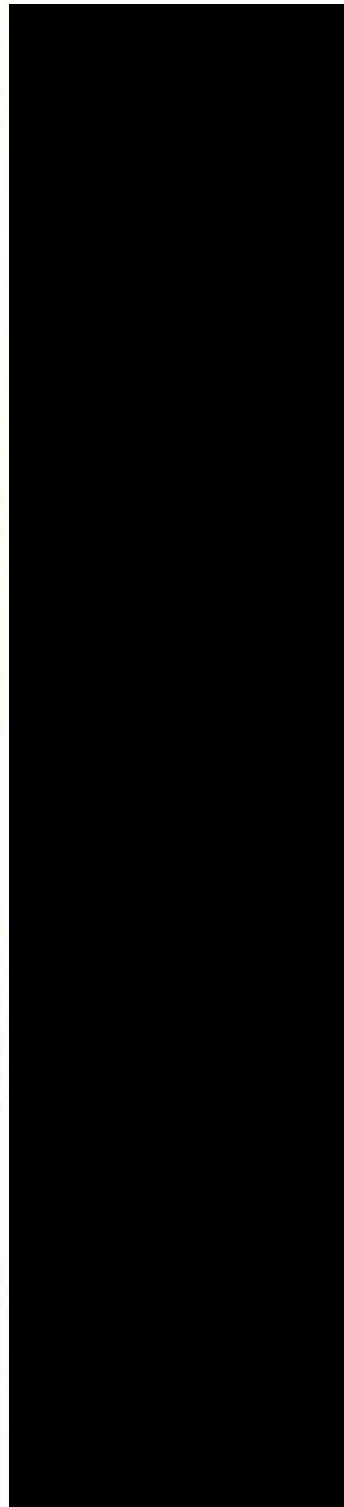
Quality Control is a key concern at our processing facility where pharmaceutical Good Manufacturing Practices (GMP's) are followed for custom blending, grinding, granulating and vacuum drying services. Our laboratory has equipment for mixing, drying and sizing as well as instruments for assay and validation of raw materials. We have complete in-house microbiological capacity, including spectrophotometers and apparatus for HPLC, A/A, UV vis., melting point, pH, and fiber products validation. All Pharmline operations revolve around our GMP Program in which raw materials are quarantined, sampled, tested, and released under the strictest conditions. A sample of every

## PHARMLINE... A little Bit About Us

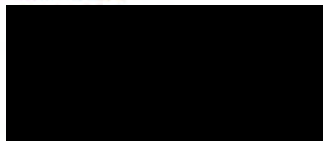
Pharmline's goal is to be *THE SOURCE* for ethical nutritional products and quality raw materials. The Company President, John Witterschein,



**PHARMLINE – Product Line**



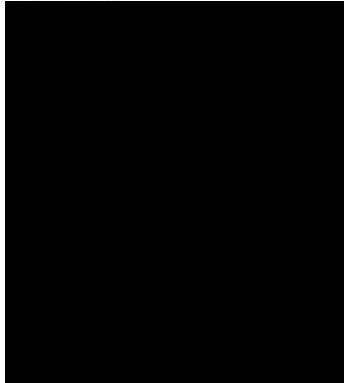
**Botanicals**



**Botanical Extracts**



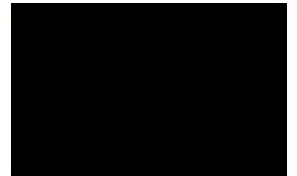
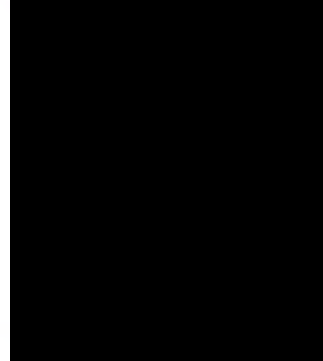
**Vitamins**



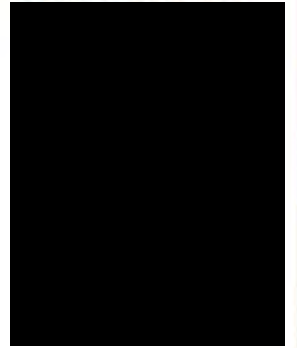
**Amino Acids/Derivatives**



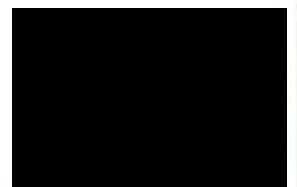
**N Acetyl-L-Cysteine**



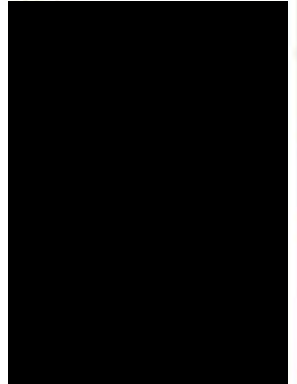
**Amino Acid Chelates**



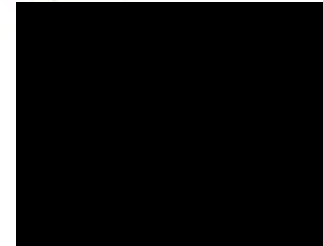
**Glandular Products**



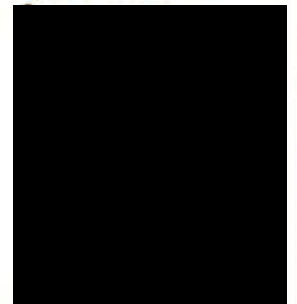
**Oils**



**Aspartates**



**Spice Powders**



**PHARMLINE, INC.**

41 Bridge Street • Florida, New York 10921  
(914) 651-4443 • FAX (914) 651-6900 • Telex 710 110 1708



Att. B



# Island Organics, Inc.

100 South Washington Avenue, Dunellen, NJ 08812 (908) 968-6664 Fax (908) 968-6866

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May 2, 1994

Mr. Michael McGuffin  
McZand Herbal Inc.  
P.O. Box 5312  
Santa Monica, CA 90409

Dear Mr. McGuffin:

Enclosed please find our catalog offering a variety of HERBS,  
HERBAL EXTRACTS, ORGANIC MINERALS and NUTRITIONAL SUPPLEMENTS.

Our many years of service providing products through brokers  
and distributors has earned ISLAND ORGANICS an excellent  
reputation for prompt reliable service and quality products.

Now, not only have we expanded our inventory, but sell directly  
to the industry at large at the same incredibly low prices.

I will give you a call next week and answer any questions you  
may have.

Very truly yours,

Pat Ransom  
Account Executive

/pr  
encl.





# now

NATURAL FOODS

## TWO BIG CHANGES

1. Starting October 1, 1993, we plan to use 100% starch foam in our order packing. No more harsh styrofoam. Thanks to Marcia at Sevenanda for convincing us.
2. Since September 1, we now have a separate 800 number for credits and customer service. Call Angela or Elva at 1-800-283-3500.

#1  
TWINPACK

## EVENING PRIMROSE

We recently tested our cold pressed Evening Primrose Oil and found it to contain exactly 9% GLA and 72% Linoleic Acid. This 500 mg softgel is identical to other national bestseller's full fatty acid profile.

|          | CODE | REG              | SALE         |
|----------|------|------------------|--------------|
| 100+100  | 1751 | ONLY             | <b>11.37</b> |
| 250 Caps | 1752 | <del>17.48</del> | <b>13.48</b> |

TWINPACK!



## PLANT UPDATE

As of mid-September, our new office/warehouse building is nearing completion. The walls are up and the roof is being finished. The building has four docks and lots of space everywhere we need it. Our early projections are for the entire building to be completed by the end of October. This will include office and production furnishings, new pallet shelving, everything we wanted but couldn't fit presently, and, maybe, a movable indoor basketball court! In any event, we plan on moving throughout the month of November in several stages. Depending on how scheduling proceeds, we should be moving our offices in mid to late November. Thank you all for your continued support that makes our move possible. Feel free to visit our new facility and we'll be more than happy to show off our new home.

Our phone and fax will remain the same. Our new address as of mid-November is:

550 Mitchell Road  
Glendale Hts., IL 60139

## WELCOME PAT!

Pat Keegan started as our new sales representative September 2nd. He is a health enthusiast who enjoys working with people and wants to be a part of our industry. His interests include basketball, jogging, and coaching in sports clinics. His past sales experience includes part-time summer work for two years at his mom's health food store. There he learned the basics and is now ready to contribute to building our company and industry. Pat will be talking to many of you, especially those in Southern California. He'll be reaching out to the biggest market in the U.S. where NOW is able to grow the most.

Welcome Pat!

#2  
TWINPACK

## B-50 CAPSULES

Get 50 mg of eight B-vitamins plus B-12, Biotin, and Folic Acid. This is basic nutrition at the lowest possible price. Our capsules are hypoallergenic, being formulated in a white rice powder base.

|          | CODE | REG             | SALE        |
|----------|------|-----------------|-------------|
| 100+100  | 0421 | ONLY            | <b>5.97</b> |
| 250 Caps | 0422 | <del>7.95</del> | <b>6.98</b> |

TWINPACK!



#3  
TWINPACK

## C-1000 CAPSULES

Get one full gram Ascorbic Acid in this capsule plus 100 mg Citrus Bioflavonoids. Buy in on a great deal to stock up for the winter season. Compare and save even on private label prices.

|          | CODE | REG             | SALE        |
|----------|------|-----------------|-------------|
| 100+100  | 0691 | ONLY            | <b>7.77</b> |
| 250 Caps | 0692 | <del>9.98</del> | <b>8.98</b> |

TWINPACK!



#4  
TWINPACK

## SUPER ODORLESS GARLIC

Our 18-month aged Garlic is a 100:1 concentrate equivalent to 5000 mg. We've added standardized Hawthorn Berry Extract and Cayenne Pepper for synergistic benefits. This Garlic is produced in Japan.

|          | CODE | REG             | SALE        |
|----------|------|-----------------|-------------|
| 90+90    | 1816 | ONLY            | <b>7.17</b> |
| 180 Caps | 1817 | <del>9.48</del> | <b>7.17</b> |

TWINPACK!



#5  
TWINPACK

## 100% NATURAL E-400 SOFTGELS

Natural Vitamin E is still provided by two suppliers: Kodak and Henkel. We buy from one of seven softgel producers, all within 3% of the labeled potency. Minimum 24° rotation.



| MIXED TOCOPHEROL           |      |                  |              |
|----------------------------|------|------------------|--------------|
| 100+100                    | 0893 | ONLY             | <b>6.48</b>  |
| 250 Caps                   | 0894 | <del>8.48</del>  | <b>7.48</b>  |
| 500 Caps                   | 0896 | <del>15.48</del> | <b>14.48</b> |
| D-ALPHA TOCOPHERYL ACETATE |      |                  |              |
| 100+100                    | 0838 | ONLY             | <b>6.48</b>  |
| 250 Caps                   | 0839 | <del>8.48</del>  | <b>7.48</b>  |
| 500 Caps                   | 0841 | <del>15.48</del> | <b>14.48</b> |

TWINPACK!



# FOUR OCTOBER SPECIALS

## WHEAT SPROUT ANTIOXIDANT

This product is produced from concentrated wheat sprouts hydroponically grown in a mineral-rich nutrient medium and high oxygen environment. This carefully controlled process maximizes the production of natural antioxidant enzymes including superoxide dismutase, catalase, glutathione peroxidase, and methionine reductase. Whole food antioxidant enzyme support is the perfect adjunct to any nutritional program, focusing upon prevention and environmental protection. Contains no soy, gluten, milk, egg, or preservatives.



The unique biological activity of Wheat Sprout Antioxidant is preserved through low temperature, non-force, dehydration and special process tableting. It takes more than one pound of fresh sprouts to yield one ounce of finished product—a 20:1 supplement that is university tested.

|          | CODE | REG.             | SALE         |
|----------|------|------------------|--------------|
| 100 Tabs | 2740 | <del>6.48</del>  | <b>5.48</b>  |
| 200 Tabs | 2742 | <del>12.48</del> | <b>10.48</b> |

## NAC N-ACETYL CYSTEINE WITH SUPPORTING NUTRIENTS

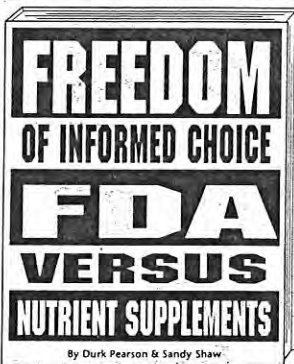
NAC is a stable form of the amino acid L-Cysteine. It is converted by the body into glutathione and then into glutathione peroxidase, an antioxidant enzyme. Our capsules contain no yeast, wheat, corn, soy, milk, egg, or preservatives. We have added trace minerals Molybdenum and Selenium for synergistic support. Compare our 600 mg with smaller size or lower potency competitors.



**EACH CAPSULE PROVIDES:**

NAC (N-Acetyl Cysteine) . . . . . 600 mg  
Molybdenum (Amino Acid Chelate) . . . . . 50 mcg  
Selenium (L-Selenomethionine) . . . . . 25 mcg

|          | CODE | REG.            | SALE        |
|----------|------|-----------------|-------------|
| 100 Caps | 0085 | <del>8.48</del> | <b>7.48</b> |



### FREEDOM OF INFORMED CHOICE THE FDA VS. NUTRIENT SUPPLEMENTS

This book offers the latest in our battle with the FDA. Durk Pearson and Sandy Shaw are two well-known and respected authors.

120 Page book

| CODE | REG. | SALE        |
|------|------|-------------|
| 8605 | ONLY | <b>2.37</b> |

### MORE THAN A SLINGSHOT

BY FRANK MURRAY

This first generation FDA book offers classic arguments on legislative activity and over-enforcement by the FDA. Frank Murray is a longtime industry writer focusing on the future of the FDA and our industry.

240 Page book

| CODE | REG. | SALE        |
|------|------|-------------|
| 8629 | ONLY | <b>2.66</b> |

## NEW SEPTEMBER SPECIALS

## AMERICAN GINSENG 5% GINSENOIDES



Today, the majority of American Ginseng is exported to China, where it is considered to be a highly treasured herb. Our American Ginseng capsules are derived from four to five year old ginseng roots cultivated in Wisconsin. The climate in Wisconsin is ideal for growing ginseng and, therefore, produces exceptionally high levels of ginsenosides. This capsule includes a minimum of 5% ginsenosides, although many lots contain over 10% ginsenosides!

|          | CODE | REG.            | SALE        |
|----------|------|-----------------|-------------|
| 50 Caps  | 4002 | <del>4.48</del> | <b>3.98</b> |
| 100 Caps | 4004 | <del>8.48</del> | <b>7.48</b> |

## CHOLINE & INOSITOL



**Two Capsules Provide:**

Elemental Choline . . . . . 250 mg  
(from 532 mg Choline Bitartrate)  
Inositol . . . . . 250 mg

Choline and Inositol are two members of the B-complex family. Each capsule contains no yeast, wheat, corn, soy, milk, egg, or preservatives.

|          | CODE | REG.            | SALE        |
|----------|------|-----------------|-------------|
| 100 Caps | 0470 | <del>3.98</del> | <b>2.98</b> |

**1994 Professional Price List  
and Catalog Supplement**



**NF FORMULAS, INC.**

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## Professional Prices

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| Glandular Formulas                      | 6 |                                       |       |

**Prices Effective  
January 15, 1994**

**Case Discount: Buy 11  
Bottles, Receive 1 Free!**

## Catalog Supplement

|                                    |    |
|------------------------------------|----|
| Multiple Vitamin-Mineral Formulas: |    |
| ████████████████████               | 9  |
| ████████████████████               | 9  |
| Mineral and Vitamin Formulas:      |    |
| ████████████████████               | 10 |
| ████████████████████               | 10 |
| ████████████████████               | 10 |
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| ████████████████████               | 10 |
| ████████████████████               | 10 |
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## Sales and Shipping Policy

### Terms

Orders are to be C.O.D. or prepaid with check, money order or valid VISA or MasterCard. Customers with approved credit are Net 10 days. Accounts with invoices not paid within 45 days may be subject to a finance charge of 1.5% per month (18% annually) and may be placed on C.O.D. status with notice. Invoices are attached to the outside of the box.

### Prices

All prices are the professional bottle price and are subject to change without notice. Case discount! buy 11 bottles and receive one bottle free.

### Ordering

Call in or fax your order at anytime. Customer Service Representatives are available to help you 8:00 am - 5:00 pm Pacific Time.

### Back Order Policy

If an item is temporarily out of stock, it will be placed on Back Order. We will ship the product as soon as it is available and there will be no additional handling charges; the shipping charge will be only the actual amount.

### Shipping Policy

United Parcel Service (UPS) is our carrier of choice. Other carriers may be used, upon request.

### Shipping Charges

There is a minimum charge for shipping and handling based on UPS Zones:

|               |        |
|---------------|--------|
| UPS Zones 2-3 | \$4.50 |
| UPS Zones 4-5 | \$5.00 |
| UPS Zones 6-7 | \$5.50 |
| UPS Zone 8    | \$6.00 |

Additional charges are based upon weight. The UPS C.O.D. fee is \$5.00. UPS rates are subject to change. Non-UPS packages will be charged actual freight costs.

### Special Delivery Services

United Parcel Service (UPS):  
2nd Day Delivery (Blue Label)  
Next Day Delivery (Red Label)  
Federal Express: all services

Call Toll-Free for a  
Customer Service Representative  
8:00 am - 5:00 pm Pacific Time:

**800 547-4891**

Customers with approved credit will be invoiced. We accept the following credit cards:



**NF FORMULAS, INC.**

9775 SW Commerce Circle ♦ Suite C-5  
Wilsonville, Oregon 97070-9602  
503 682-9755 ♦ FAX 503 682-9529

## PROFESSIONAL PRICE LIST

4

## Acidophilus Formulas

| PRODUCT NAME | DESCRIPTION | SIZE        | PRICE | CODE |
|--------------|-------------|-------------|-------|------|
|              |             | 90 Capsules | \$    |      |

## Enzyme Formulas

| PRODUCT NAME | DESCRIPTION | SIZE         | PRICE | CODE |
|--------------|-------------|--------------|-------|------|
|              |             | 100 Capsules | \$    |      |
|              |             | 60 Capsules  | \$    |      |
|              |             | 60 Tablets   | \$    |      |

## Omega-3 &amp; 6 Fatty Acids and Other Oils

| PRODUCT NAME | DESCRIPTION | SIZE             | PRICE | CODE |
|--------------|-------------|------------------|-------|------|
|              |             | 90 Capsules      | \$    |      |
|              |             | 8.5 Fluid Ounces | \$    |      |
|              |             | 100 Capsules     | \$    |      |

## Amino Acid Formulas

| PRODUCT NAME | DESCRIPTION                | SIZE           | PRICE   | CODE  |
|--------------|----------------------------|----------------|---------|-------|
|              |                            | 60 Capsules    | \$      |       |
|              |                            | 60 Capsules    | \$      |       |
|              |                            | 60 Capsules    | \$      |       |
|              |                            | 60 Capsules    | \$      |       |
| N.A.C.       | 600 mg N-Acetyl-L-Cysteine | 60 Capsules    | \$ 8.00 | 21301 |
|              |                            | 60 Capsules    | \$      |       |
|              |                            | 60 Capsules    | \$      |       |
|              |                            | 6 Fluid Ounces | \$      |       |
|              |                            | 60 Capsules    | \$      |       |
|              |                            | 100 Capsules   | \$      |       |
|              |                            | 60 Capsules    | \$      |       |
|              |                            | 60 Capsules    | \$      |       |
|              |                            | 180 Capsules   | \$      |       |

## Botanical Specialty Formulas

| PRODUCT NAME | DESCRIPTION | SIZE         | PRICE | CODE |
|--------------|-------------|--------------|-------|------|
|              |             | 180 Capsules | \$    |      |
|              |             | 120 Capsules | \$    |      |
|              |             | 50 Capsules  | \$    |      |
|              |             | 100 Tablets  | \$    |      |
|              |             | 60 Capsules  | \$    |      |
|              |             | 60 Capsules  | \$    |      |
|              |             | 90 Tablets   | \$    |      |
|              |             | 60 Capsules  | \$    |      |
|              |             | 60 Capsules  | \$    |      |
|              |             | 90 Tablets   | \$    |      |
|              |             | 240 Tablets  | \$    |      |
|              |             | 120 Capsules | \$    |      |
|              |             | 60 Tablets   | \$    |      |
|              |             | 60 Capsules  | \$    |      |
|              |             | 30 Lozenges  | \$    |      |
|              |             | 60 Tablets   | \$    |      |
|              |             | 30 Capsules  | \$    |      |



# CONFIDENTIAL

2832 Dow Avenue  
Tustin, California 92680 U.S.A.  
(714) 832-9700  
TeleFax (714) 731-8482

## CERTIFICATE OF ANALYSIS

DATE: 5/6/94

CUSTOMER: COUNTRY LIFE

PRODUCT NAME: #1686B 750mg N A C CAPSULE

LOT NUMBER: 34279

FORMULA NUMBER: 4734

| <u>PHYSICAL PARAMETERS</u> | <u>SPECIFICATIONS</u>                              | <u>FOUND</u>   |
|----------------------------|--|--|
| Appearance:                | Size 00 clear HS capsule filled with white powder. | Conforms   |
| Average Weight:            | USP limits of variation                            | (Gross) <u>0.8888 gm.</u><br>(Net) <u>0.7638 gm.</u> |

| <u>EACH CAPSULE CONTAINS</u> | <u>CLAIM/CAPSULE</u> | <u>FOUND</u> |
|------------------------------|----------------------|--------------|
| N-Acetyl-Cysteine            | 750 mg               | 750 mg*      |

\*By Input

Date of manufacture: 5/6/94

EXPIRATION DATE (in bulk): 5/96

This is not a vegetarian capsule (Gelatin is from animal source).

The ingredients in this product does not contain any animal, yeast, corn, wheat, soy, dairy or egg material.

**Michael F. Nassar, Ph.D., B.C.N.S.**  
Vice President  
Science and Technology

MAY 16 1994

COFACNS-4734  
ELJ 4/29/94





2832 Dow Avenue  
Tustin, CA 92680 USA  
(714) 832-9700  
Telex: 277714, Cable: VITATECH

Att. E

BULK LABEL

**CONFIDENTIAL**

**Manufactured For:**

Country Life  
28300 B INDUSTRIAL BLVD.  
HAYWARD, CALIFORNIA 94545

**Product:** #1686 B 750 mg N-acetyl-cysteine, HSC

**Containing:**

Label No.: 4734

Formula No.: 4734

Net Contents: 76,822

Containers: 7

Lot No.: 34279

Purchase Order No.: #7931  
12,000

Carton Contains:

Expiration Date: 5-96

AMOUNT

N-acetyl-cysteine 750 mg

INGREDIENTS:

N-acetyl-cysteine, magnesium stearate, silicon dioxide and gelatin.

This product is not be sold for treatment, prevention, cure or mitigation of disease.

Special consumer label instructions may apply. Consignee is fully responsible for consumer labeling in accordance with applicable State and Federal regulations.

**WARNING:** Keep this all drugs out of children's reach. In case of an accidental overdose, seek professional assistance or contact a poison control center immediately.

This capsule is very hygroscopic. It may discolor upon aging or upon exposure to moisture. Special care must be taken not to expose it to moisture while consumer packaging. use dessicant bags in consumer packaging.

Consignee in accepting this shipment, acknowledges and agrees, that the formulation was made at the expressed direction of the consignee. VitaTech International, Inc., assumes no responsibility whatsoever, regarding the client formulation and client holds harmless VitaTech International from any action of law which may be brought against this product.

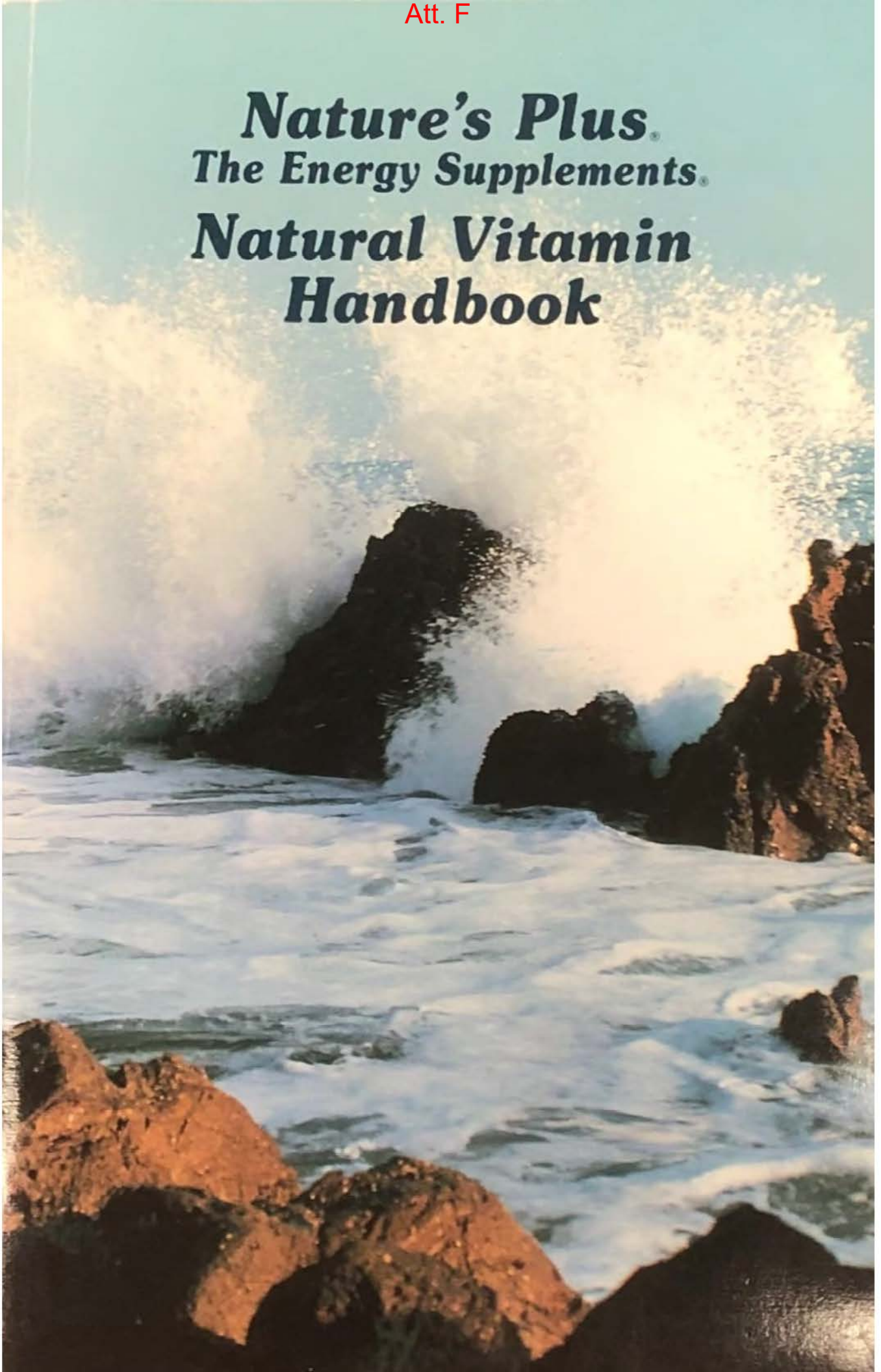
Consignee must store in a cool (25° C or less) and dry (25% rel. humidity or less) place.

**Terms and Conditions:**

This is a bulk shipment labeled as such and is for repackaging or reprocessing only. The label hereon does not necessarily constitute proper label declaration with respect to the intended purpose, dosage or route or method of administration of the repackaged or reprocessed goods or products. The purchaser, in relabeling, must assume all responsibility in this regard for compliance with the Federal Food, Drug and Cosmetic Act and such State Acts as may apply and as such Acts are consi-

tuted and effective at the time of labeling. Incorporation of purchaser-supplied raw material in this shipment is done with purchaser's assumption of full liability and responsibility for such raw material, its potency, purity and conformance with applicable Federal and State laws. Other Terms and Conditions relating to this shipment are covered in the applicable Order Acknowledgement and shipment documentation. Said Terms and Conditions are specifically applicable to this shipment.

***Nature's Plus.***  
***The Energy Supplements.***  
***Natural Vitamin***  
***Handbook***



## Inosine 600 mg. Caps

One Capsule Contains:

100% Pure Crystalline Inosine . . . . . 600 mg.  
HXR (hypoxanthine riboside)

Hypo-Allergenic • Pharmaceutical Grade

Contains No Yeast, Wheat, Corn, Soy, Milk, Salt, Sugar or Starch

**Bottles of 30 #4959**

## Oxy-Nectar™ Ten Stage Antioxidant Beverage

Oxy-Nectar is the first scientifically engineered ten-stage antioxidant beverage ever developed. Each delicious mixed berry serving supplies a concentrated profile of Vitamins, Minerals, Amino Acids and Bioflavonoids, including Beta Carotene, Pycnogenol and the OptiZinc brand of Zinc Monomethionine. This potent nutrient blend is then synergistically fortified with Standardized Herbs, Fruit and Vegetable Extracts, Whole Foods, Plant Enzymes and Cell Pigments, for ultimate antioxidant protection.

Nutritional Information Per Serving:

Servings Per Container: Approximately 18

Calories . . . . . 107  
Protein . . . . . 10 g.  
Carbohydrate . . . . . 17 g.  
Fat . . . . . 0 g.

### ANTIOXIDANT VITAMIN BLEND

**Vitamin C** (corn free) (fortified with rose hips, West Indian cherry, mango and guava) . . . . . 600 mg.  
**Beta Carotene** (carrot, Dunaliella Salina) (fortified with broccoli and spinach) (supplying 10,000 I.U. vitamin A activity) 60 mg.  
**Vitamin E** (natural) . . . . . 200 I.U.

### ANTIOXIDANT MINERAL BLEND

**Zinc** (monomethionine)† . . . . . 15 mg.  
**Selenium** (selenomethionine) . . . . . 50 mcg.

### ANTIOXIDANT BIOFLAVONOID BLEND

**Citrus Bioflavonoid Complex** (active flavonols, flavonones, flavones & naringen - 44%) . . . . . 50 mg.  
**Quercetin** (saphora japonica) . . . . . 25 mg.  
**Rutin** (saphora japonica) . . . . . 25 mg.  
**Hesperidin** (citrus) . . . . . 20 mg.  
**Eriocitrin** (citrus) . . . . . 5 mg.  
**Pycnogenol**†† (pinus maritima) (standardized 85-95% proanthocyanidins) . . . 5 mg.

### ANTIOXIDANT HERBAL BLEND

**Astragalus** (astragalus membranaceus) 150 mg.  
**Ligustrum** (ligustrum lucidum) . . . . . 150 mg.  
**Shiitake Mushroom** (lentinus edodes) 100 mg.  
**Echinacea** (echinacea purpurea) . . . . . 100 mg.  
**Schizandra** (schizandra chinensis) . . . . . 100 mg.  
**Ginkgo Biloba** (50:1)(standardized 24% ginkgo flavonglycosides) . . . . . 10 mg.

### ANTIOXIDANT VEGETABLE BLEND

**Broccoli 10:1** (brassica oleracea) (naturally rich in sulforaphane) . . . . . 150 mg.

**Spinach 10:1** (spinacia oleracea) . . . . . 50 mg.  
**Chinese Cabbage 10:1** (brassica chinensis) . . . . . 50 mg.  
**Carrot 10:1** (daucus carota) . . . . . 50 mg.  
**Tomato** (naturally rich in lycopene) . . . . . 50 mg.  
**Garlic**††† (odorless) (equivalent to a minimum of 2½ times its weight in fresh garlic) . . . . . 25 mg.

### ANTIOXIDANT FRUIT BLEND

**Mixed Wild Berry Extract** (European red wine grape, blackberry, red raspberry and black raspberry) (standardized 20% polyphenols, 4% anthocyanosides) . . . . . 250 mg.  
**Bilberry** (standardized 25% anthocyanosides) . . . . . 10 mg.

### ANTIOXIDANT AMINO ACID BLEND

**NAC** (N-acetyl-cysteine) . . . . . 15 mg.  
**L-Methionine** (free form amino acid) . . . 10 mg.  
**L-Glutathione** (free form amino acid) . . . 10 mg.

### ANTIOXIDANT WHOLE FOOD BLEND

**Spirulina** (blue-green micro-algae) . . . . . 50 mg.  
**Dried Green Barley Juice** (organically grown, low-temperature dried) . . . . . 50 mg.  
**Chlorella** (broken cell wall) . . . . . 25 mg.

### ANTIOXIDANT PLANT ENZYME BLEND

**Oxidase** (brown rice fermentation) (5,000 units per gram) . . . . . 10 mg.  
**Catalase** . . . . . 5 mg.  
**Peroxidase** . . . . . 5 mg.

### ANTIOXIDANT FOOD SOURCE

**CELL PIGMENT BLEND**  
**Chlorophyll** (spirulina, chlorella, barley grass) . . . . . 685 mcg.  
**Carotenoids** (spirulina, chlorella, barley grass) . . . . . 4 mcg.

† **OPTIZINC™**

U.S. Patent Nos. 3,941,818, 4,021,569 and 4,764,633. OptiZinc is a trademark of InterHealth Company.

Yeast Free • Vegetarian



U.S. Patent No. 4,698,360.

††† **PURE GAR™**

**1.3 lb. (594 g) Can #4961**

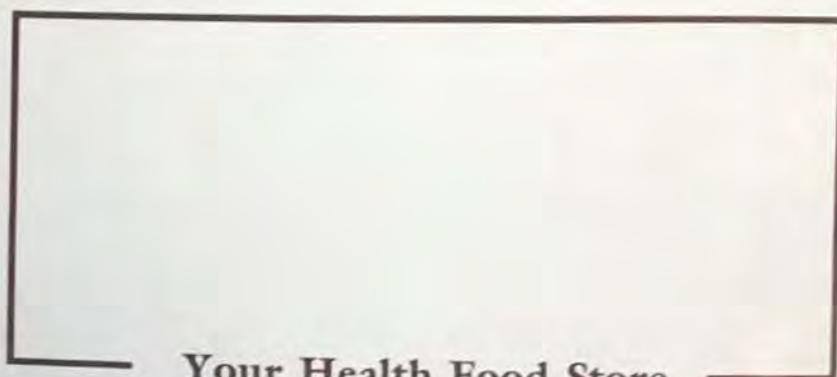
## All Brands Of Natural Vitamins Are Not Alike!

Purity, quality and manufacturing techniques vary considerably from one company to another. NATURE'S PLUS products are derived from the highest quality natural sources available. We at NATURE'S PLUS seek out and formulate the finest of all natural vitamins from the far corners of the earth. This is done to bring you unsurpassed quality, regardless of cost.

It is NATURE'S PLUS policy to assure you of the highest possible purity and quality. All NATURE'S PLUS natural vitamin products are formulated utilizing the finest manufacturing techniques available, to lock in potency and stability. In accordance with this policy, we at NATURE'S PLUS stand by the following guarantee:

### Guarantee

- NATURE'S PLUS guarantees all vitamin and mineral potencies meet or exceed federal regulations.
- NATURE'S PLUS has taken steps to prevent damaging oxidation of products.
- NATURE'S PLUS utilizes the most modern techniques to seal out the damaging effects of moisture and light.
- NATURE'S PLUS products are manufactured under the highest standards possible, using modern techniques of quality control in our own manufacturing facility.



**Nature's Plus<sup>®</sup>**  
**The Energy Supplements<sup>®</sup>**

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2500 Grand Avenue, Long Beach, CA 90815-1764 (310) 494-2500

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