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).

October 8, 2021

The American Herbal Products Association (AHPA) respectfully submits comments in support of the June 1, 2021, citizen petition submitted by the Council for Responsible Nutrition (CRN) (FDA Dkt. No. FDA-2021-P-0523) seeking a determination by the U.S. Food and Drug Administration (FDA) that a product consisting of or containing N-acetylcysteine (NAC)[1] that otherwise meets the definition of "dietary supplement" at 21 U.S.C. § 321(ff) is not excluded from that definition under 21 U.S.C. § 321(ff)(3)(B).

AHPA agrees with CRN that 21 U.S.C. § 321(ff)(3)(B) does not have retroactive effect. As such, this provision does not exclude from the definition of "dietary supplement" products that contain or consist of articles—such as NAC—that were already being marketed as foods or dietary supplements before the enactment of the Dietary Supplement Health and Education Act of 1994, regardless of whether such articles were approved or authorized for investigation as new drugs prior to their marketing in the food supply. Even if FDA disagrees, and without conceding the lawfulness of such a position, AHPA would urge FDA to issue a regulation finding that NAC is a lawful dietary supplement pursuant to 21 U.S.C. § 321(ff)(3)(B). *See* 21 C.F.R. § 10.30(e)(3) (authorizing the Commissioner to "grant such other relief or take other action as the petition warrants").

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.

I. Background

On October 25, 1994, the Dietary Supplement Health and Education Act of 1994 (DSHEA)[2] was enacted to provide a framework under the Federal Food, Drug, and Cosmetic Act (FFDCA) for regulation of dietary supplements as a subcategory of foods. In part, DSHEA defines "dietary supplement" to mean a product (other than tobacco) that: (i) contains a dietary ingredient; (ii) is intended for ingestion to supplement the human diet; (iii) is not represented for use as a conventional food or as a sole item of a meal or the diet; and (iv) is labeled as a dietary supplement. 21 U.S.C. § 321(ff).

[1] NAC is also referred to as N-acetyl-L-cysteine or acetylcysteine.

[2] Pub. L. 103-417, 108 Stat. 4325 (Oct. 25, 1994).

The "dietary supplement" definition, however, excludes products that contain or consist of any article (i) "that is approved as a new drug under [section 505 of the FFDCA]" or (ii) "authorized for investigation as a new drug . . . for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public" that was not "before such approval . . . or authorization marketed as a dietary supplement or as a food." 21 U.S.C. § 321(ff)(3)(B) (hereinafter, "prior drug exclusion provision").

NAC is a substance that has been marketed as or in dietary supplements since at least 1991.[3] Indeed, we understand that FDA was aware of NAC's presence in dietary supplements prior to DSHEA's enactment.[4] NAC continues to be included as an ingredient in numerous dietary supplement products on the market today.[5]

According to FDA's Orange Book, an inhaled form of NAC was first approved by FDA on September 14, 1963, as a drug for use in patients with abnormal, viscid, or inspissated mucous secretions in various pulmonary conditions.[6] Since then, FDA has approved NAC drugs in both injectable[7] and tablet[8] forms as treatments for acetaminophen overdose.

Despite the fact that NAC had been marketed as or in dietary supplements well before DSHEA's enactment, FDA has taken the position that "NAC products" are excluded

---

[3] *See, e.g.*, Pharmline, Inc. Product Line (Aug. 1991) (listing "N Acetyl-L-Cysteine" under "Amino Acids/Derivatives") (relevant pages attached as Att. A); *see also* NF Formulas, Inc., Professional Price List (Jan. 15, 1994) (listing "N.A.C." or "N-Acetyl-L-Cysteine" under "Amino Acid Formulas") (relevant pages attached as Att. B); Island Organics, Inc., Catalog (May 2, 1994) (listing "N-Acetyl Cysteine" under "Vitamins and Nutritional Supplements") (relevant pages attached as Att. C); NOW Foods Inc. Sell Sheet (Sept. 1993) (listing "NAC N-ACETYL CYSTEINE" product as available for purchase) (attached as Att. D). AHPA has not performed an exhaustive review of the products in the U.S. food supply prior to October 15, 1994, that consisted of or contained NAC. From these few examples, FDA can assume the existence of other products containing or consisting of NAC marketed at that time. *See, e.g.*, Att. D ("Compare our **600 mg** with smaller size or lower potency competitors.").

[4] *See, e.g.*, FDA, 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 (May 12, 1993), at 3 (including NAC in examples of dietary supplements "containing complex mixtures of ingredients").

[5] For instance, the NIH Dietary Supplement Label Database identifies 78 currently marketed products containing NAC. *See* NIH Dietary Supplement Label Database, https://dsld.od.nih.gov/search/acetylcysteine/bWFya2V0X3N0YXR1cz1vbl9tYXJrZXQvZW50cnlfZGF0ZT0yMDExLDIwMjEvc29ydD1tYXRjaC9wYWdlX3NpemU9MjAv (last accessed Sept. 30, 2021).

[6] Drugs@FDA, NDA 013-601 (Mucomyst), https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=013601 (last accessed Sept. 30, 2021); *see also* NIH DailyMed, Acetylcysteine (inhalant), https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f56b4087-db48-4fd7-84ec-9c927962b805 (last accessed Sept. 30, 2021).

[7] *See, e.g.*, Drugs@FDA, NDA 021-439 (Acetadote), https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=021539 (last accessed Sept. 30, 2021).

[8] Drugs@FDA, NDA 207-916 (Cetylev), https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=207916 (last accessed Sept. 30, 2021).

from the "dietary supplement" definition under the prior drug exclusion provision. For instance, in July 2020, FDA issued a series of Warning Letters to manufacturers of various NAC products claiming to treat hangovers, stating as follows:

> FDA has concluded that NAC products are excluded from the dietary supplement definition under section 201(ff)(3)(B)(i) of the Act [21 U.S.C. § 321(ff)(3)(B)(i)]. Under this provision, if an article (such as NAC) has been approved as a new drug under section 505 of the Act [21 U.S.C. § 355], then products containing that article are outside the definition of a dietary supplement, unless before such approval that article was marketed as a dietary supplement or as a food. NAC was approved as a new drug under section 505 of the Act [21 U.S.C. § 355] on September 14, 1963. FDA is not aware of any evidence that NAC was marketed as a dietary supplement or as a food prior to that date.[9]

FDA took this same position in its February 2, 2011, response to a new dietary ingredient notification for NAC, concluding that "N-Acetylcysteine, the active moiety, and N-Acetylcysteine ethyl ester[] are excluded from the dietary supplement definition under the exclusion clause in 21 U.S.C. 321(ff)(3)(B) and therefore may not be marketed as or in a dietary supplement."[10]

To AHPA's knowledge, FDA has not expressly addressed the question of whether DSHEA, and the prior drug exclusion provision in particular, has retroactive effect.

II. The Prior Drug Exclusion Provision Does Not Apply to Articles that Were Marketed as or in Conventional Foods or Dietary Supplements Prior to DSHEA's Enactment

The Supreme Court of the United States has long "embraced a presumption against statutory retroactivity" and "declined to give retroactive effect to statutes burdening private rights unless Congress had made clear its intent." *Landgraf v. USI Film Products*, 511 U.S. 244, 271-273 (1994); *see also Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988) ("…[C]ongressional enactments and administrative rules will not be construed to have retroactive effect unless their language requires this result."). This presumption recognizes the "unfairness of imposing new burdens on persons after the fact." *Landgraf* 488 U.S. at 265. FDA cannot overcome this presumption in interpreting the prior drug exclusion provision.

First, nothing in DSHEA requires, or indicates that Congress intended, that the prior drug exclusion provision be interpreted to exclude from the definition of "dietary

---

[9] FDA Warning Letter to Purple Biosciences, LLC (July 23, 2020), *available at* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/purple-biosciences-llc-593772-07232020; *see also, e.g.*, FDA Warning Letter to LES Labs (July 23, 2020), *available at* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/les-labs-593764-07232020.

[10] Ltr. from Dan D. Levy, CFSAN, FDA, to Yadon Arad, Tiara Pharm., Dkt. No. FDA-1995-S-0039 (Oct. 21, 2010).

supplement" products already on the market when DSHEA was enacted. Indeed, FDA acknowledged that DSHEA was intended to strike a balance by both "prohibit[ing] the marketing as dietary supplements of articles that have gained recognition in the marketplace as new drugs by either being approved or studied as new drugs," while also "permit[ting] continued marketing of an article that was marketed as a food or dietary supplement even if that article is **subsequently shown** to have therapeutic benefit and is studied or approved as a new drug."[11] Any concerns Congress had about "a disincentive to the often significant investment needed to gain FDA approval of new drugs" on the part of drug manufacturers clearly did not apply to drugs already approved when DSHEA was enacted.[12]

Second, excluding NAC—a dietary ingredient that was approved for use as a drug in 1963 and marketed as or in dietary supplements since as early as 1991—from the definition of "dietary supplement" would have impermissible retroactive effect as doing so would "attach[] new legal consequences to events completed before [the statute's] enactment" and would "take[] away or impair[] vested rights acquired under existing laws." *Landgraf*, 511 U.S. at 269-70. DSHEA does not contain any language indicating that Congress intended the prior drug exclusion provision to suddenly render unlawful *all* dietary supplements marketed pre-October 25, 1994, merely by virtue of containing ingredients approved as new drugs before their use in the food supply. To be sure, no court has come to such a far-reaching conclusion, and none has squarely addressed the question of whether the prior drug exclusion provision was intended to have retroactive effect.[13]

Third, legislative history confirms that Congress did not intend for DSHEA to retroactively impact otherwise lawful dietary supplements already on the market. Congress added the prior drug exclusion provision to the "dietary supplement" definition to discourage drug manufacturers from "avoid[ing] the drug approval process by marketing drug products as dietary supplements."[14] As Congress explained,

---

[11] Ltr from William B. Schultz, FDA, to S.M. Pape, Patton Boggs, Dkt. No. 97P-0441 (May 20, 1998) (emphasis added).

[12] *Id*.

[13] *See, e.g.*, *Pharmanex v. Shalala*, 221 F.3d 1151 (10th Cir. 2000) (considering whether the phrase "an article that is approved as a new drug" in the prior drug exclusion provision includes active ingredients as well as finished drug products in the context of a drug previously approved in 1987); *U.S. v. Syntrax Innovations, Inc*., 149 F. Supp. 2d 880 (E.D. Mo. 2001) (acknowledging that the defendant conceded that an investigational new drug application in effect since 1990 excluded a substance from the dietary supplement definition in a case concerning the appropriate scope of injunctive relief in a civil forfeiture action).

[14] S.R. Rep. No. 103-410 (1994) at 20. Subsequent to the Senate Report, a Statement of Agreement was printed in the Congressional Record stating that the Statement "comprises the entire legislative history" for DSHEA and that "[i]t is the intent of the chief sponsors of the bill ... that no other reports or statements be considered as legislative history for the bill." Statement of Agreement, 140 Cong. Rec. S14801 (Oct. 7, 1994), reprinted in 1994 U.S.C.C.A.N. 3523. At least one court has referred to the Senate Report in interpreting the prior drug exclusion provision while acknowledging the Statement of Agreement. *See Pharmanex v. Shalala*, 221 F.3d 1151, 1158 (10th Cir. 2000).

> . . . a substance which has been marketed as a dietary ingredient in a dietary supplement, or otherwise as a food, does not lose its status as a food (assuming it is intended for use as a dietary supplement or other food purpose as shown by its promotional materials) just because FDA approves the substance for use as an active ingredient in a new drug . . . Those types of products would be drugs because they would be promoted with drug claims. They would, and should, have no effect on the food status of a properly-labeled dietary supplement.[15]

In other words, the prior drug exclusion provision was intended to clarify that the status of existing dietary supplements (as foods) would be unaffected by *future* drug development.

Indeed, by way of example, Congress explained that, "if ever FDA should eventually approve Vitamin C as a drug to treat cancer, Vitamin C properly would also continue to be available as a dietary supplement (food) product, so long as it is promoted as a dietary supplement without disease prevention claims."[16] Vitamin C was first approved as a drug in 1947 and, since the 1962 amendments to the FFDCA, at least as early as 1985.[17] Similarly, Vitamin D—another common dietary supplement on the market—appears to have been first approved as a drug in 1941 and, since the 1962 amendments to the FFDCA, at least as early as 1973.[18] Congress could not have reasonably expected that, upon DSHEA's enactment, all Vitamin C and D dietary supplements would be removed from the market absent evidence that they were marketed prior to the 1940s (or 1970s/1980s). AHPA is also not aware of any efforts by FDA to prohibit the marketing of such products without such evidence.

For these reasons, FDA should determine that NAC is not excluded from the definition of "dietary supplement" under 21 U.S.C. § 321(ff)(3)(B).[19]

---

[15] *Id*. at 20-21.

[16] *Id*.

[17] *See* Drugs@FDA, NDA 006071 (Berocca PN (containing ascorbic acid among other active ingredients)), https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=006071 (last accessed Sept. 30, 2021); Drugs@FDA, NDA 018440 (M.V.C. 9+3 (containing ascorbic acid among other active ingredients)), https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=018440#2518 (last accessed Sept. 30, 2021).

[18] *See* Drugs@FDA, NDA 003-444 (ergocalciferol), https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=003444 (last accessed Sept. 17, 2021); Drugs@FDA, ANDA 080884 (Deltalin (ergocalciferol)), https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=080884 (last accessed Sept. 27, 2021).

[19] FDA has previously concluded that a product containing NAC is a "dietary supplement that includes vitamins or other nutritional substances" and thus meets the definition of "substance" under 21 CFR 101.14(a)(2). Ltr. from Douglas Balentine, CFSAN, FDA to Thomas B. Shea, Sevo Nutraceuticals, Inc., Dkt. No. FDA-2016-Q-1523 (Dec. 12, 2018).

III. In the Alternative, FDA Should Issue a Regulation Finding that Products Consisting of or Containing NAC Are Lawful Dietary Supplements

If FDA nevertheless concludes that the prior drug exclusion provision has retroactive effect, AHPA asserts, without conceding the lawfulness of such a position, that FDA should issue a regulation finding that NAC is a lawful dietary supplement pursuant to 21 U.S.C. § 321(ff)(3)(B). *See* 21 C.F.R. § 10.30(e)(3) (authorizing the Commissioner to "grant such other relief or take other action as the petition warrants"). NAC has been marketed as a dietary supplement (or a dietary ingredient in dietary supplements) for decades and has not posed any reported safety concerns to date.[20] Moreover, the continued marketing of NAC as a dietary supplement does not pose any risks of disincentivizing the development of drugs containing an active ingredient first approved nearly six decades ago. In fact, NAC's use as an ingredient in dietary supplements does not appear to have impacted any post-DSHEA drug development; drugs containing NAC were developed and approved *after* DSHEA even while the substance continued to be marketed as and in dietary supplements.[21]

While AHPA understands that FDA has never exercised its authority under 21 U.S.C. § 321(ff)(3)(B) to issue a regulation finding that an article is a lawful dietary supplement, NAC would prove an ideal candidate for such a regulation given its demonstrated safety profile and existence in the food supply for decades, including prior to DSHEA's enactment. By promulgating a regulation deeming NAC a lawful dietary supplement, FDA would simply maintain the status quo and allow important, widely-used dietary supplements to remain on the market for consumer use.

* * * * *

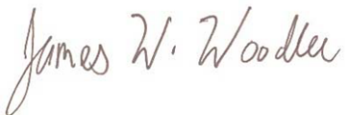
AHPA greatly appreciates the opportunity to present comments on this matter. AHPA staff and counsel will make themselves available at any mutually convenient time to further address any of the topics addressed herein. Please feel free to contact us if clarification or additional discussion is needed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

[20] *See, e.g.*, NIH Fact Sheet for Health Professionals, Dietary Supplements in the Time of COVID-19, https://ods.od.nih.gov/factsheets/COVID19-HealthProfessional/ (last updated Aug. 17, 2021) ("No safety concerns have been reported for products labeled as dietary supplements that contain NAC.").

[21] *See, e.g.*, *supra* note 7 (NDA 021539 (Acetadote (injectable), approved Jan. 23, 2004); note 8 (NDA 207916 (Cetylev (tablet), approved Jan. 29, 2016).

Respectfully submitted,

Michael McGuffin
President, American Herbal Products Association
mmcguffin@apha.org



James W. Woodlee
Samantha N. Hong
Kleinfeld, Kaplan and Becker, LLP
General Counsel, American Herbal Products Association
wwoodlee@kkblaw.com
shong@kkblaw.com

Att. A

PHARMLINE, Inc.

The Source

- For Fine Nutritional Products -

August 1991

[redacted]

[redacted]

[redacted]

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, 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 apparati 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

Att. A

PHARMLINE – Product Line

[redacted]

[redacted]

Botanicals

[redacted]

Botanical Extracts

[redacted]

Vitamins

[redacted]

Amino Acids/Derivatives

[redacted]

N Acetyl-L-Cysteine

[redacted]

Glandular Products

[redacted]

Aspartates

[redacted]

[redacted]

Amino Acid Chelates

[redacted]

[redacted]

Oils

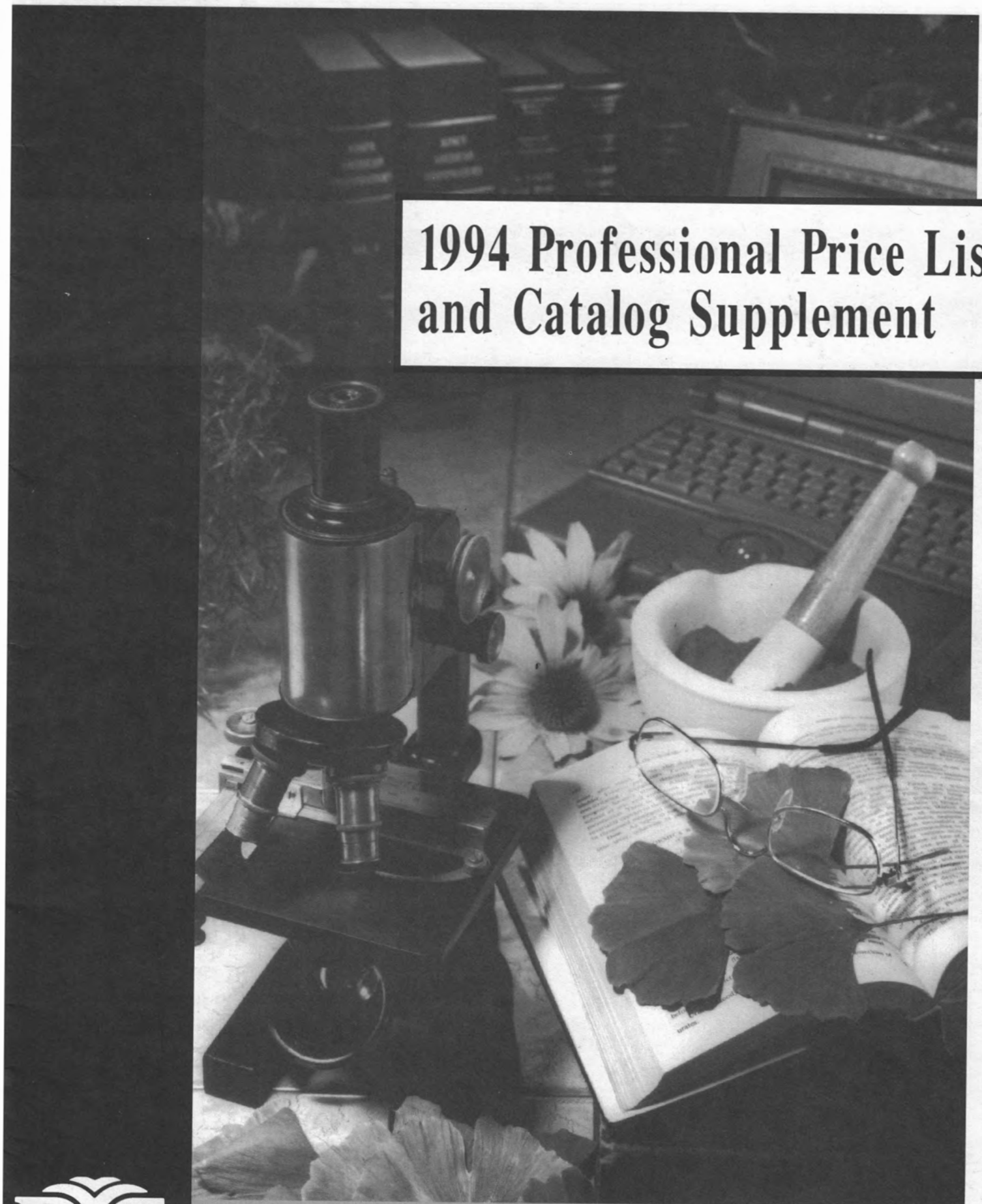
[redacted]

Spice Powders

[redacted]

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

Att. B



1994 Professional Price List and Catalog Supplement

NF FORMULAS, INC.

Index

Professional Prices

Prices Effective January 15, 1994

Case Discount: Buy 11 Bottles, Receive 1 Free!

Catalog Supplement

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:

VISA MasterCard

NF FORMULAS, INC.
9775 SW Commerce Circle ◆ Suite C-5
Wilsonville, Oregon 97070-9602
503 682-9755 ◆ FAX 503 682-9529

Att. B

Acidophilus Formulas

PRODUCT NAME	DESCRIPTION	SIZE	PRICE	CODE
[redacted]	[redacted]	90 Capsules	$ [redacted]	[redacted]

Enzyme Formulas

PRODUCT NAME	DESCRIPTION	SIZE	PRICE	CODE
[redacted]	[redacted]	100 Capsules	$	
[redacted]	[redacted]	60 Capsules	$	
[redacted]	[redacted]	60 Tablets	$	

Omega-3 & 6 Fatty Acids and Other Oils

PRODUCT NAME	DESCRIPTION	SIZE	PRICE	CODE
[redacted]	[redacted]	90 Capsules	$	
[redacted]	[redacted]	8.5 Fluid Ounces	$	
[redacted]	[redacted]	100 Capsules	$	

Amino Acid Formulas

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

Botanical Specialty Formulas

PRODUCT NAME	DESCRIPTION	SIZE	PRICE	CODE
[redacted]	[redacted]	180 Capsules	$	
[redacted]	[redacted]	120 Capsules	$	
[redacted]	[redacted]	50 Capsules	$	
[redacted]	[redacted]	100 Tablets	$	
[redacted]	[redacted]	60 Capsules	$	
[redacted]	[redacted]	60 Capsules	$	
[redacted]	[redacted]	90 Tablets	$	
[redacted]	[redacted]	60 Capsules	$	
[redacted]	[redacted]	60 Capsules	$	
[redacted]	[redacted]	90 Tablets	$	
		240 Tablets	$	
[redacted]	[redacted]	120 Capsules	$	
[redacted]	[redacted]	60 Tablets	$	
[redacted]	[redacted]	60 Capsules	$	
[redacted]	[redacted]	30 Lozenges	$	
[redacted]	[redacted]	60 Tablets	$	
[redacted]	[redacted]	30 Capsules	$	

Att. C

Island Organics, Inc.

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

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

Pat Ransom
Account Executive

/pr
encl.

Branch Office: (201) 796-1807 Fax (201) 796-8894

Att. C

Island Organics, Inc.

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

Vitamins and Nutritional Supplements

N-Acetyl Cysteine

Att. D

October 1993 Specials

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

TWINPACK!

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	**11.37**
250 Caps	1752	~~17.48~~	**13.48**

#2 TWINPACK

B-50 CAPSULES

TWINPACK!

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

	CODE	REG	SALE
100+100	0421	ONLY	**5.97**
250 Caps	0422	~~7.95~~	**6.98**

#3 TWINPACK

C-1000 CAPSULES

TWINPACK!

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	**7.77**
250 Caps	0692	~~9.98~~	**8.98**

#4 TWINPACK

SUPER ODORLESS GARLIC

TWINPACK!

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	**7.17**
180 Caps	1817	~~9.48~~	**7.17**

#5 TWINPACK

100% NATURAL E-400 SOFTGELS

TWINPACK!

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.

100% NATURAL SOURCE VITAMIN E

MIXED TOCOPHEROL			
100+100	0893	ONLY	**6.48**
250 Caps	0894	~~8.48~~	**7.48**
500 Caps	0896	~~15.48~~	**14.48**
D-ALPHA TOCOPHERYL ACETATE			
100+100	0838	ONLY	**6.48**
250 Caps	0839	~~8.48~~	**7.48**
500 Caps	0841	~~15.48~~	**14.48**

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!

1-800-999-8069 Minimum Order — $95 Free Freight $250

Att. D

FOUR OCTOBER SPECIALS

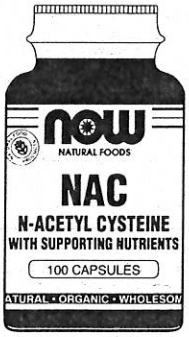
WHEAT SPROUT ANTIOXIDANT

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	~~6.48~~	**5.48**
200 Tabs	2742	~~12.48~~	**10.48**

NAC
N-ACETYL CYSTEINE
WITH SUPPORTING NUTRIENTS

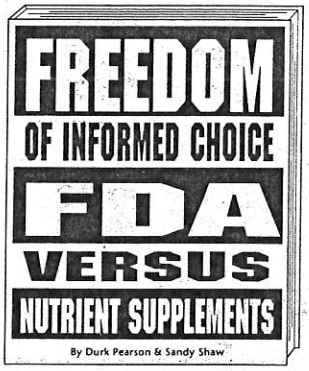


NAC is a stable form of the amino acid L-Cysteine. It is converted by the body into glutathione and then into glutathione peroxidase, an antioxidant enzyme. Our capsules contain no yeast, wheat, corn, soy, milk, egg, or preservatives. We have added trace minerals Molybdenum and Selenium for synergistic 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	~~8.48~~	**7.48**



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	**2.37**

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	**2.66**

NEW SEPTEMBER SPECIALS

AMERICAN GINSENG
5% GINSENOSIDES

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	~~4.48~~	**3.98**
100 Caps	4004	~~8.48~~	**7.48**

CHOLINE & INOSITOL

Two Capsules Provide:

Elemental Choline (from 532 mg Choline Bitartrate)	250 mg
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	~~3.98~~	**2.98**