



Council for Responsible Nutrition

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Dockets Management Branch (HFA 305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: DOCKET NO. 2004N-0454, PREMARKET NOTIFICATION FOR NEW DIETARY INGREDIENTS

The Council for Responsible Nutrition (CRN) is a leading trade association for the dietary supplement industry, representing many mainstream manufacturers of dietary ingredients and of national brand name and private label dietary supplements, as well as a number of marketers with an international scope. Attached to our written comments is a list of our member companies and some of the products they provide to consumers.

We congratulate FDA for the recently announced initiatives intended to more fully implement the Dietary Supplement Health and Education Act (DSHEA) and to provide industry with clear and consistent guidance that will improve every company's ability to comply with the requirements of the law in a manner that meets the agency's expectations. This in turn will provide an added measure of protection for consumers and will increase the public's ability to have confidence in the dietary supplements used on a regular basis by more than half the population.

CRN is prepared to commit resources to being actively involved in every phase of FDA's ongoing development and implementation of these initiatives, and our member companies have great energy and expertise to bring to the overall effort. We view today's meeting as an important first step in the portion of the initiative relating to New Dietary Ingredients (NDIs). In this effort, FDA and all stakeholders will be seeking to clarify some critical definitions and identify appropriate models for demonstrating that new dietary ingredients and the dietary supplements containing them "will reasonably be expected to be safe." CRN will have extensive comments to the Docket (No. 2004N-0454) on the numerous specific questions posed by FDA in announcing this meeting. Our member companies will be affected by every detail of FDA's approach to these issues, but for today's meeting we want to focus on some broad principles upon which we believe agreement must be reached before the details can be adequately considered.

The purpose of DSHEA was to ensure consumer access to a wide variety of safe dietary supplements and to provide consumers with more information about these products. In order to ensure broad access to products, dietary ingredients already on the market were

“grandfathered” as old ingredients, and a new process for oversight of NDIs was established. Dietary ingredients were excluded from the definition of “food additives,” and the NDI system was established as an entirely separate and distinct notification process. From these provisions of DSHEA it is clear that Congress intended to affirm the safety of a broad array of existing dietary ingredients and establish a notification process for new dietary ingredients that was distinct from the food additive approach and also markedly less burdensome than the food additive approach. These intentions must be respected and preserved, as FDA now moves toward better defining dietary ingredients, NDIs, and notification requirements. At this time, CRN and one of our sister trade associations, the Consumer Healthcare Products Association (CHPA) are also submitting for the record a set of comments prepared by our outside legal counsel Peter Barton Hutt of Covington & Burling regarding the need to respect and preserve the fundamental assumptions of DSHEA as the agency turns its attention to full implementation of the NDI provisions of the law.

DIETARY INGREDIENTS AND NEW DIETARY INGREDIENTS (NDIs)

DSHEA defines a dietary supplement very broadly as “a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)...”

These categories are and were intended to be broad, and must remain broad. Definitions for these categories must be direct and literal and must not be artificially restricted to accomplish purposes other than merely defining the scope or potential scope of the category. Safety will be an important factor in determining whether an ingredient may be marketed and whether a new ingredient notification is adequate for its purpose, but safety is not a factor in defining the category *per se*. CRN and its members are troubled by a tendency in the FDA announcement to combine definitional and safety issues. We believe more clarity will be achieved if safety is rightly viewed as a separate consideration, not as a factor that would restrict the scope of the category definition. Some examples may clarify this point.

One category of dietary ingredients is “minerals.” This term encompasses a large number of elements that for the most part occur naturally as compounds and not as pure elements. Calcium, for example, is an essential mineral that occurs naturally in several forms, including calcium carbonate. It is also marketed in forms that are not naturally-occurring but are the result of processing, such as calcium citrate. Thus, the compound in which a mineral may be marketed is not limited to those that occur naturally. While calcium is an essential mineral, essentiality in human nutrition is not a condition of inclusion as a mineral, for purposes of the definition. For example, other minerals such as nickel, silicon, tin, and vanadium are commonly included in many national brands and store brands of multivitamin/multimineral supplements and are grandfathered ingredients, having been present in such products for many years.

Another broad category of dietary ingredients is “botanicals.” Commonly marketed (and grandfathered) botanicals include garlic, ginseng, ginkgo, and Echinacea. The category also includes botanicals such as comfrey and chapparal and kava, about which some safety concerns have been raised. These safety concerns are separate considerations that apply to their appropriate use, not to whether they are encompassed in the definition.

Section E of the definition refers to “a dietary substance for use by man to supplement the diet by increasing the total dietary intake.” CRN views the term “dietary substance” to refer to anything in food, whether the food itself is commonly consumed by most people or only rarely consumed by a small subgroup of consumers, and whether the particular substance is a major or minor or trace constituent of the food. We also view the term as encompassing synthetic equivalents of the naturally-occurring substances. Another dietary supplement ingredient that is not a common food component but that we believe to be covered by this section of the definition is shark cartilage. A colloquy in the Senate (page S 16609 of the Congressional Record of October 24, 1990), during the debate over the Nutrition Labeling and Education Act (NLEA) illustrates the broad scope of the term “other similar nutritional substances” as used in 403(r)(5)(D) of NLEA. In that colloquy, it was agreed that the term “other similar nutritional substance” in NLEA included substances such as “primrose oil, black currant seed oil, cold pressed flax seed oil, ‘Barleygreen’ and similar nutrition powdered drink mixes, coenzyme Q-10, enzymes such as bromelain and quercetin, amino acids, pollens, propolis, royal jelly, garlic, orotates, calcium OEAP (colamine phosphate), glandulars, hydrogen peroxide (H2O2), nutritional antioxidants such as superoxide dismutase (SOD), and herbal tinctures.” A similarly broad view should be taken of the term “dietary substance” as used in Section E of DSHEA’s definition of dietary ingredients.

The overwhelming majority of dietary supplements on the market today in the U.S. are composed of “old” dietary ingredients. These are ingredients that were marketed in the U.S. prior to October 15, 1994. These ingredients are “grandfathered” by DSHEA in the sense that they are not subject to any requirements for submitting safety information to FDA, as is required for NDIs. In order to be grandfathered, an old ingredient must meet three tests. It must have been marketed (1) as a dietary ingredient, defined by DSHEA as an ingredient in a dietary supplement; (2) it must have been marketed in the U.S.; (3) and it must have been present in the U.S. market as a dietary supplement prior to October 15, 1994.

DSHEA does not specifically define “old” dietary ingredients, except by exclusion from the definition of a “new dietary ingredient.” In DSHEA, a “new dietary ingredient” is “a dietary ingredient that was not marketed in the United States before October 15, 1994.” Just to hammer this point home, DSHEA goes on to say that the term “does not include any dietary ingredient which was marketed in the United States before October 15, 1994.”

If the definition of dietary ingredient is broad, as we believe it must be, then the scope of grandfathered ingredients is also broad. There is no indication in DSHEA that there are

any circumstances under which an ingredient marketed in the U.S. in a dietary supplement before October 15, 1994, would ever become a “new dietary ingredient.” FDA nevertheless poses numerous questions intended to probe the conditions under which this might occur. CRN believes these questions require further consideration and discussion, and we will be engaging our member companies and other stakeholders in such discussions during the remainder of the comment period on this issue. Doubtless today’s presentations will be helpful to all of us in this process.

In some of FDA’s recent warning letters, the agency has taken the position that some ingredients are not grandfathered because they were not “legally marketed” prior to October 15, 1994. DSHEA does not actually specify that only “legally marketed” dietary ingredients are considered to be old ingredients. The purpose of grandfathering old ingredients was to provide a safe harbor for all ingredients marketed in dietary supplements in the U.S. before the passage of DSHEA. As a case in point, consider the essential trace minerals, selenium and chromium. In numerous instances in the decades prior to DSHEA, FDA adopted the position that these ingredients were neither GRAS substances nor approved food additives and that their use in dietary supplements was therefore technically not permitted. Nevertheless, these minerals were widely marketed as components of dietary supplements, and FDA has now established official RDIs for them. Selenium and chromium are grandfathered dietary ingredients, despite the fact that FDA may not have viewed that their marketing prior to DSHEA as being technically “legal.” Another case in point pertains to amino acids. Under FDA food additive regulations, amino acids could only be added to foods for a few specified purposes, yet amino acids were and still are widely marketed as dietary supplements. They are a permissible category of ingredients under DSHEA, and many are grandfathered, despite the fact that FDA prior to DSHEA took the position that their marketing as supplements was not technically “legal.”

At least three of the industry trade associations have a reference list of ingredients their member companies believe to be grandfathered, including CRN, AHPA, and NNFA. These lists are considered to be advisory in nature and not definitive or exclusive lists. They are generic lists and do not include any information about factors such as dosage or concentration or method of extraction. These lists serve as a general reference for the dietary supplement industry, especially as we move more than a decade away from the key date established in DSHEA for determining whether an ingredient is old or new. We do not believe, however, that it would be possible at this late date to create a more authoritative list. Additionally, we do not believe there should be a list that is considered official or authoritative in the sense of limiting the ability of a company to document old ingredient status for a substance that may not be on the list.

IDENTIFICATION OF THE NEW DIETARY INGREDIENT

FDA poses some questions regarding the information that should be provided in a new dietary ingredient notification regarding the chemical characterization of the ingredient, the conditions of cultivation for a botanical, and the processing applied to the ingredient. At a later point in this process, CRN will submit detailed comments on these issues. In

general, there should be identification of ingredient or product characteristics related to safety. However, at this point, we want to emphasize that some of the extensive information outlined in the Federal Register notice may be desirable but not essential, and some of it may be considered proprietary. As we continue to work with FDA to define the information needed in the notification, we urge the agency to include some affirmative reassurance regarding the protection of proprietary information.

INFORMATION ABOUT THE DIETARY SUPPLEMENT

A dietary ingredient is by definition an ingredient in a dietary supplement, and FDA contemplates that an NDI notification should include some information about its intended use in the finished product. We agree that this is appropriate, since DSHEA specifies that the manufacturer or distributor wishing to market an NDI must submit information “which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.” (emphasis added) However, CRN notes that the NDI notification may be submitted by a supplier of the ingredient or by a manufacturer in the pre-launch phase of product development, and it may not be possible at that point to submit actual labels or labeling, although it would be possible to describe the intended uses. Thus, FDA should not specifically require submission of a label or labeling in all cases.

ESTABLISHING A REASONABLE EXPECTATION OF SAFETY

The core question for consideration at this meeting and during the ensuing comment period is: What type of information should be included in an NDI notification in order to establish a reasonable expectation of safety?

FDA poses a number of excellent questions that assist in clarifying the types of information that may be useful in establishing safety based on a history of use or based on other evidence including scientific studies. At a future time, CRN will be submitting more detailed comments on many of these specifics. For purposes of this meeting, we want to emphasize that the relevance or importance of many of these questions will vary depending on the nature of the dietary ingredient, its similarity to existing ingredients, and the likelihood of potential safety concerns. We recommend that questions such as those posed in the Federal Register notice should be included in a guidance document as suggestions for issues to be considered and not as absolute requirements for inclusion in a notification. Also, it should be clarified that it is appropriate for evidence of traditional use to include evidence relating to foreign uses as well as U.S. uses. We urge the agency to include language in any guidance document affirming the utility and appropriateness of including foreign references as well as examples of foreign uses of dietary supplements.

In examining FDA’s description of the studies that might be considered, industry members who are familiar with food additive and GRAS petitions see a lot of similarity to the requirements set forth in the “Red Book,” while industry members who are familiar with pharmaceutical products see a lot of similarity to the information required for a New

Drug Application (NDA). CRN believes these models would not be appropriate for NDI notifications for dietary supplements. As mentioned earlier, DSHEA deliberately excluded dietary ingredients from the definition of food additives and then established a separate notification procedure, and there should be no appearance in the current proceeding that the agency is tending back toward a food additive model. CRN has been assured verbally that this is not the agency's intent, but we nevertheless want to reiterate this concern very clearly for the record in this proceeding.

In public presentations, some FDA staff have indicated that they consider the safety standard for NDIs to be essentially the same as the safety standard for food additives and GRAS substances. CRN does not agree with this conclusion. The safety standard for food additives and GRAS substances is to demonstrate "reasonable certainty of no harm." Congress, in passing DSHEA, did not choose to use this language but instead crafted a different standard, namely that the ingredient will "reasonably be expected to be safe." The difference in language implies an intent that the standard be somewhat different. In addition to establishing a different standard, DSHEA established a different process for dietary ingredients. FDA affirmatively approves food additives, thus putting the agency's official imprimature on the ingredient. FDA does not formally approve NDIs. Thus, the notification is not for the purpose of persuading the agency to affirmatively approve an NDI, but is rather to demonstrate to the agency that the manufacturer or distributor seeking to market the ingredient has arrived at a reasonable conclusion regarding an expectation of safety.

There are models other than the food additive and NDA models that may be useful in considering different ways to demonstrate a reasonable expectation of safety. In reaching GRAS determinations for food ingredients, for example, a manufacturer may rely heavily on an expert advisory group to draw conclusions regarding safety. A company may make its own GRAS determination without notifying FDA, or may notify FDA and seek public listing. While the GRAS determination process is closely related to the food additive petition process in terms of content, it does include the additional and useful element of an expert committee evaluation.

A model used by the EPA new chemicals program involves structure/activity analysis to evaluate likely health outcomes based on comparison to other chemicals with analogous structures. Such an analysis could play a role when the NDI is a single chemical compound.

Canada's Natural Health Products Directorate is reviewing the safety of numerous dietary supplements and other natural health products and has developed a protocol for evaluating the safety of such ingredients and products, which may also have value as a model. This process has only become effective this year, but should be monitored by FDA to determine its possible utility for the U.S.

In FDA's evaluation of health claims, the agency requested additional information about psyllium and about stanol and sterol esters, without requiring all the types of information typically provided for food additives, and in FDA's guidance on new plant varieties

produced by biotechnology, considerable reliance is placed on the manufacturer's evaluation of the new plant's relationship to existing varieties, with little or no requirement for clinical studies in most cases.

One strong recommendation CRN and its member companies would make regarding the NDI notification process is that FDA should signal to the industry a willingness to meet and discuss particular applications with the industry sponsors, in order to provide more assurance both to the agency and to the company that the information submitted will be considered relevant and sufficient for its purpose.

OTHER DEFINITIONS

FDA seeks information regarding the definition of some other terms used in DSHEA in describing permissible dietary ingredients. CRN will be submitting more information in our detailed comments addressing these terms. At this time, however, we want to make the point that terms such as "constituent" and "metabolite" should be understood broadly, and any resulting issues having to do with safety or other considerations should be dealt with directly, not used as reasons for restricting the definition itself.

GUIDANCE FOR PREPARATION OF AN NDI NOTIFICATION

FDA inquires whether there is a need for a guidance document or amendment of the current requirements for submission of an NDI notification. CRN endorses the seven recommendations listed in the meeting notice, all of which would improve the format and content of the notifications, making it more likely that a notifier would provide meaningful information and making it easier for the agency to review the notification.

CONCLUSIONS

Again, CRN congratulates FDA for undertaking this initiative and for fully involving all stakeholders in the discussion. It is through cooperative efforts that regulatory approaches can best be developed that will serve the needs of the agency, and industry, and most importantly of the consuming public.

Council for Responsible Nutrition Member Companies

Manufacturers of Finished Products	
Member Company	Products
<u>Access Business Group/Nutriline</u>	Nutriline®, Trim Advantage®
<u>Accucaps Industries Limited</u>	Private Label Manufacturer of Vitamins and Minerals, Oils, Specialty Supplements, and Herbals
<u>Arkopharma, LLC</u>	Sokoja®, Azinc®, Potensium®, Arkocaps®, Memoboost®, Turbodiet®
<u>B&C Nutritional Products, Inc.</u>	Private Label Manufacturer of Vitamins and Minerals, Specialty Supplements, and Herbals
<u>Bayer HealthCare LLC</u>	One-A-Day®, Flintstones®
<u>Bio San Laboratories Inc.</u>	Private Label Manufacturer of Vitamins and Minerals, MegaFood®, DailyFoods®, Essentials®
<u>Cadbury Adams USA LLC</u>	Halls Defense® Vitamin C
<u>Enzo Nutraceuticals</u>	Enzogenol®
<u>GNC Incorporated</u>	GNC ProPerformance®, Preventive Nutrition®, Herb Plus®, GNC Natural Brand®, Total Lean®, Mega Men®, Womens Ultra Mega®, Herbal Plus®
<u>GNLD International</u>	Carotenoid Complex®, GR ² Control®
<u>Herbalife International</u>	Direct seller of Inner and Outer Nutrition® products including ShapeWorks™ family of personalized protein-based Nutritional Shake Mixes plus targeted supplements including Total Control®, Snack Defense™ and Garden 7™
<u>Jamieson Laboratories Ltd.</u>	Mega Cal®, Vita Vim®, Promedis™
<u>Kemin Consumer Care, L.L.C.</u>	Satise®
<u>Leiner Health Products Inc.</u>	Private Label Manufacturer and Branded Contract Manufacturer of Vitamins, Minerals and Nutritional Supplements.
<u>Mannatech, Inc.</u>	Glycentials®, Ambrotose®, Phyt•Aloe®, CardioBALANCE®, ImmunoStart®, Glyco•Bears®, Phyto•Bears®, EM•Pact®, GlycoLEAN®, Plus®, Ambrostart®, Sport®, Emprizone®
<u>Natural Alternatives International Inc.</u>	Pathway to Healing®, Chopra Center Essentials™, Private Label Manufacturer
<u>NBTY, Inc.</u>	Nature's Bounty®, Vitamin World®, Puritan's Pride®, Holland & Barrett®, Nutrition Headquarters®, American Health® and Nutrition Warehouse®, Sundown®, Osteo Bi-Flex®, Pokemon®, Private Label Manufacturer

Council for Responsible Nutrition Member Companies

Manufacturers of Finished Products	
Member Company	Products
<u>Nu Skin International Inc./Pharmanex LLC</u>	LifePAK®, Phamanex Solutions®, TRA the right approach®
<u>Nutraceutical Corporation</u>	Solaray®, KAL®, NaturalMax®, VegLife®, Premier One®, Sunny Green®, Natural Sport®, ActiPet®, Action Labs®, Miztique®, Ultimate Nutrition® and Thompson®, Private Label Manufacturer
<u>Nutramax Laboratories, Inc.</u>	Cosamin® DS , Senior Moment®
<u>Perrigo Company</u>	Private Label Manufacturer and Branded Contract Manufacturer
<u>Pharmaton Natural Health Products</u>	Ginsana®, Ginsana Gold®, Ginkoba®, Kyolic®, Venastat®, SAME®
<u>Pharmavite LLC</u>	Nature Made®, Nature's Resource®, Private Label Manufacturer, Olay™ Vitamins
<u>Proper Nutrition, Inc.</u>	SeaCure®, SeaVive®
<u>Pulse Nutrition</u>	Pulse® Water + Nutrients (Vitamins and Minerals)
<u>Rainbow Light Nutritional Systems</u>	Active Health®, Complete Nutritional System®, Complete Prenatal System®, Nutristars®, Performance Energy®, Women's Answer® and other Single Nutrient, Herbal, and Specialty Supplements
<u>Ross Products</u>	Ensure®, Glucerna®, Similac® Infant Formulas, AdvantEdge®, Myoplex®, Body-for-Life®, ZonePerfect®
<u>Shaklee Corporation</u>	CorEnergy®, Mood-Lift®, Vita-Lea®, CoQHeart®, Immunity Formula I®, Herb-Lax®, Optiflora®, EZ-Gest®, Shaklee Fitness®, Performance®, Physique®, Liver DTX®, Fiber Plan®
<u>Swiss Caps USA, Inc.</u>	Contract Manufacturer of Solid Dosage Forms of Nutritionals
<u>Tom's of Maine</u>	Botanicals
<u>VitaTech International, Inc.</u>	Private Label Manufacturer
<u>Weider Nutrition International, Inc.</u>	Schiff®, Schiff® Move Free®, Tiger's Milk®, Weider®, Fi Bar®
<u>Wyeth</u>	Centrum®, Centrum Silver®, Centrum Performance®, Centrum Kids®, Caltrate®

Council for Responsible Nutrition Member Companies

Suppliers	
Member Company	Products/Ingredients/Services
<u>Access Business Group - Trout Lake Farms</u>	Grower and Processor of Botanical Ingredients, Ocean Essentials®
<u>Albion Laboratories, Inc.</u>	Bulk Minerals
<u>American Laboratories, Inc.</u>	Processor and Supplier of Enzymes (Pancreatin USP, Pepsin FCC, Plant and Fungal Enzymes), Thyroid USP, Peptones, Liver and Glandulars
<u>Archer Daniels Midland Company</u>	Vitamin E, Soy Isoflavones, Lecithin
<u>B&D Nutritional Ingredients, Inc.</u>	Natural Source Vitamin E, Lecithin, Phytosterols, Grape Skin and Grape Seed, NuTriene™ Tocotrienols, FloraGLO® Lutein, Enzogenol®, Fibersol™, Betanad® Natural Beta Carotene, SAWA™ Wasabia, Mera Astaxanthin, Soy Isoflavones
<u>BASF Corporation</u>	Vitamins A, C, D, E, K, B Vitamins, Beta-carotene, Lycopene, Omega-3 Fatty Acids, Lysine, Caffeine, Excipients, Beverage Clarifiers & Stabilizers, Antioxidants, and Postharvest Produce Coatings
<u>Bioriginal Food & Science Corporation</u>	Supplier of Essential Fatty Acids (EFAs)
<u>Biotron Laboratories, Inc.</u>	Supplier of Various Mineral Amino Acid Chelates
<u>Capsugel</u>	Encapsulated Products and Capsules
<u>Cardinal Nutrition</u>	OptiMSM®, Supplier of Raw Ingredients
<u>Cargill Health & Food Technologies</u>	Soy Isoflavones, Chondroitin, Vitamin E
<u>Cognis Nutrition & Health</u>	Natural Vitamin E, Tonalin® CLA, Vegapure®, Sterols/Sterol Esters, Lutein Esters, Natural Mixed Carotenoids, ALA, Botanicals, Emulsifiers, Food Technology Ingredients
<u>Colorcon</u>	Excipients, Colors, Coating Systems, Printing Inks
<u>Daiichi Fine Chemicals, Inc.</u>	B Vitamins, Vitamin D, Carotenoids
<u>DSM Nutritional Products, Inc.</u>	Vitamins A, C, D, & E, B Vitamins (RoCoat™ Coated B vitamins, Carotenoids (redivivo™ Lycopene, OPTISHARP™ Zeaxanthin, FloraGLO® Lutein, CaroCare® Natural Beta-carotene, BetaTab 20 Beta-carotene), Omega-3 Fatty Acids (ROPUFA®), Nutraceuticals (LAFTI® Second Generation Probiotics, TEAVIGO™ EGCG)
<u>E.T. Horn Company</u>	Bulk Ingredients Including: Calcium Carbonate, Glucosamine, Cellulose
<u>Generichem Corporation</u>	Bulk Supplier of Minerals
<u>Indena USA, Inc.</u>	Botanical Ingredient Supplier

Council for Responsible Nutrition Member Companies

Suppliers	
Member Company	Products/Ingredients/Services
<u>Kaneka America Corporation</u>	Supplier of Co-Enzyme Q10
<u>Kemin Foods, L.C.</u>	Lutein - FloraGLO®, Antioxidants
<u>Linnea, Inc.</u>	Botanicals Supplier
<u>Lonza, Inc.</u>	Supplier of L-Carnitine and B Vitamins
<u>Mingtai Chemical, LLC</u>	Microcrystalline Cellulose, Comprecal®, Crosscarmellose Sodium
<u>Nashai Biotech LLC</u>	Supplier of Ingredients Including TeaFlavin®
<u>Nutrinoa</u>	Supplier of Omega-3 PUFA (Nutrinoa DHA®) and high-intensive sweetener (Sunett®)
<u>Nutrition 21, Inc.</u>	Chromax® Chromium Picolinate, Zinmax® Zinc Picolinate, Selenomax® High Selenium Yeast, Selenopure® l-selenomethionine, Zenergen™ Chromium Picolinate plus CLA
<u>Nurture, Inc.</u>	OatVantage™ Oat Bran Concentrate; Nurture® 1500
<u>Ocean Nutrition Canada Ltd.</u>	Omega-3 Fatty Acids
<u>Omya, Inc.</u>	Supplier of Calcium Carbonate
<u>Polyphenolics</u>	MegaNatural® Gold Grape Seed Extract, MegaNatural® Grape Pomace Extracts, MegaNatural® Rubired Grape Juice Extract, MegaNatural® Red Wine Extract
<u>Pronova Biocare, a.s.</u>	Omega-3 Fatty Acids - EPAX®, Triomega®, Pikasol®, Omacor®
<u>Rhodia, Inc.</u>	Calcium Phosphate, Probiotics
<u>Seven Seas Limited</u>	Fish Oils, Multivitamins, Evening Primrose Oil, Herbals, ActionPlan50+®
<u>Shionogi Qualicaps, Inc.</u>	Global Supplier of Two-Piece Capsules and Capsule Machinery
<u>Stauber Performance Ingredients</u>	Supplier of Vitamins, Minerals, Amino Acids, and Specialty Products
<u>Unigen Pharmaceuticals, Inc.</u>	Univestin®, Lasoperin®, Unirespin®, UltrinTG®, DiAfin®, Pervarin®, Immuno-10®, Aloewhite®, UltrinHG®
<u>Zila Nutraceuticals, Inc.</u>	Ester-C® Calcium Ascorbate, Ester-E® Tocopheryl Phosphates