**NF Quality**

**Breaking through Nutritional Boundaries!**

At Nutritional Frontiers we take tremendous pride in the partnership we have with all of our clients. It is an incredible time right now for natural healing and the supplement industry and we are at the forefront.

The quality control standards with the new cGMP regulations are at an all-time best and the technology with new delivery systems are maximizing compliance, absorption and results. We have surveyed thousands of people requesting non-tablet supplements and we have listened. During the past year we have introduced over 30 new formulations utilizing cutting edge and unique delivery systems such as powders, liquids, sprays, sustained released tabs and chewable’s.

All of our formulas are 100% guaranteed to meet label claim! We must look beyond just meeting label claim and we do so by using therapeutic dosing, bioactive forms of ingredients and all natural inactive ingredients. Our professional team has over 150 years of experience and is consistently learning the newest research. We are the first concierge service for natural healthcare professionals and patients. At Nutritional Frontiers the healthcare professional and patient always come first.

Nutritional Frontiers provides a 100% money back guarantee on all products and services.

**Example of Quality**

**Choosing the Right Ingredients
Therapeutic Dose
Finished Product**

**Choosing the Right Ingredients**

What do we mean by “Choosing” the right ingredients? Aren’t all ingredients pretty much the same?

Matching the ingredient in the product with the ingredient from the study.  For a product to work, it is important to make sure that the ingredients in the formula are the same one that were used in clinical study. This may seem reasonable enough to go without mention, but surprisingly not all companies in the industry take the time to do so. The source (where it comes from), Amount (dosage level) and type (compound or structure) are all vital components in developing high quality products.

* Source - It is natural or synthetic? How was it grown, harvested and processed?
* Amount - Does it live up to Therapeutic Dose (Please read TD section below)
* Type - Not all calciums are the same - Calcium Carbonate is different from Microcrystalline Hydroxyapatite or Chelates in that it does not absorb well and is harder for the body to utilize. Making it, and other ingredients with similar ...

**Therapeutic Dose**

What does this mean to me?

Simply put, the therapeutic dose of an ingredient is the range of how much of that ingredient must be taken daily to receive a benefit. This amount is established through research and clinical trials where patient results are measured at different dosing.

In many cases, even when the right ingredients are chosen for a formula, companies don’t put enough of each ingredient in their product to produce the desired result (i.e. it would be like ordering a salad at lunch made from the best organic materials, then eating only one bite. Is that going to be enough to sustain you?)

**Example: Fish oil**

Fish oils are very popular today, but how many live up to quality? To make sense of this, we need to first understand that its not the amount of oil itself that make these products beneficial, but the total strength of the active ingredients, namely the omega 3s EPA and DHA.

Based on clinical research, the established therapeutic dose is for the oil to contain at least 750mg of a combined EPA / DHA, taken 2 to 3 times a day (i.e. 1,500mg - for maintenance of moderate conditions. 2,250 mg for severe or chronic conditions).

**Looking at other products in the market:**

Some only list the amount of oil - no way to tell how much active components you are getting.
Others have between 50 - 150mg per dose, meaning you would have to take 10 - 30 softgels each day to receive a benefit.
We have made our product at 780mg per each softgel, meeting the requirements for 2 a day dosing.

**Finished Products**

* Micro Analysis
* Impurities / Heavy Metals
* Meeting Label Claim

This is where all the had work meets-up with our ability to stand behind the completed formula - testing of finished goods in a Certificate of Analysis or C of A.

* Microbiology
* Heavy Metals
* Stability
* PCBs and Dioxins
* Disintegration
* Label Claim

**QC and Lab Assays**

**Nutritional Frontiers is committed to Quality, Integrity, Research and Service.**

Every formula and product from Nutritional Frontiers is produced in a cGMP certified manufacturing facility. cGMP is defined as current Good Manufacturing Practices and are now regulated by the FDA as part of the DSHEA in 1993. This guarantees our partners in health that every formula is produced using the best technology and utilizing the highest quality control standards. What this means for the consumer is that every product is 100% guaranteed for purity and potency.

All formulas are created with therapeutic dosages based upon cutting edge science and research. Nutritional Frontiers’ unique formulations are based upon the latest research to provide comprehensive patient solutions. We offer comprehensive and unique therapeutic formulas with preferred delivery technology. Nutritional Frontiers utilizes formulas with all of the ingredients you need with the proper dosage and unique delivery systems. Nutritional Frontiers is known for offering the highest quality control standards. This is done in order to guarantee everything 100% for purity and potency. Nutritional Frontiers sets the standard in the industry for integrity by providing a 100% guarantee on every formula for purity and potency.

**NF Pure**

**Are All Supplements Created Equal?**

Unfortunately, a large percentage of the nutritional supplements available to the public are of poor quality. The vitamin and mineral pills sold in most grocery stores, discount stores, and even some sold in health food stores have the following possible problems, (as verified by independent research analysis, and reported in newspapers and exposed on such television programs such as 60 Minutes): low potency, products not containing what is alleged on the label, nutrients not in usable form (not bioavailable), added colorings, including alumnium-based dyes, artificial flavorings, wax, coal tar derivatives, antifreeze, and are not digestible due to cheap and excessively strong binders and fillers, which mean they pass right through you without being absorbed or utilized.

**Quality. Integrity. Research. Service.**

Our dedicated team consists of a unique blend of all disciplines including D.C., M.D., PhD., Biochemists, RN, Pharma D and Naturopathic doctors. Our mission is to create, develop and provide safe, effective and therapeutic natural solutions plus educational programs to healthcare professionals and patients worldwide.

**CERTIFIED NF PURE**- When you see Certified NF pure on our label you know that this formula is 100% guaranteed for purity, is free of any contaminants and meets label claim for potency every time.

**NF Logos**

|  |  |  |  |
| --- | --- | --- | --- |
| All Natural | Dairy Free | Gluten Free | Vegetarian |
| Chewable | Liquid | Powder | Vegetable Capsules |

**Gluten Free**

It is estimated that nearly one of every 130 individuals globally may be sensitive to gluten, a protein found in grains like [wheat](http://en.wikipedia.org/wiki/Wheat), [kamut](http://en.wikipedia.org/wiki/Kamut%22%20%5Ct%20%22_blank) and [spelt](http://en.wikipedia.org/wiki/Spelt), [barley](http://en.wikipedia.org/wiki/Barley), [rye](http://en.wikipedia.org/wiki/Rye), malts and [triticale](http://en.wikipedia.org/wiki/Triticale). It can be a main ingredient or can be used as a [food additive](http://en.wikipedia.org/wiki/Food_additive) in the form of a flavoring, stabilizing or thickening agent.

Gluten allergies or sensitivities may trigger reactions that range from general discomfort to immune responses, chronic inflammation, and nervous system imbalances, to an autoimmune disease of the small intestine (Celiac Disease), which could interfere with the absorption of nutrients. If left untreated, can lead to disruption of multiple organ systems and a number of serious health issues hampering the quality of one’s life.

Simply identifying gluten sensitivity can be challenging, let alone eliminating it from the diet when its use in the food industry is so widespread. Nutritional Frontiers products are gluten free. If you have questions about a specific product please contact Nutritional Frontiers at 412-922-2566

**Dairy Free**

Lactose Intolerance - Dairy products contain varying amounts of the milk sugar called lactose. During normal digestion, the enzyme lactase breaks the milk sugar down in the small intestine. People with lactose intolerance, however, do not produce enough lactase, so the undigested food moves into the colon where bacteria breaks it down. As a result, the individual experiences gas, abdominal cramping and diarrhea within 30 minutes to two hours after eating.

Milk Allergy - A milk allergy differs from lactose intolerance in several ways. First, the person reacts to the protein in the milk, rather than to the sugar. Second, milk allergies most often occur in infants while the risk of lactose intolerance increases with age. Third, when the patient's immune system attacks the milk proteins, symptoms can be severe and life-threatening. A person with a milk allergy must avoid all dairy products, even in small amounts.

**Vegetarian**

Vegetarians today come from all walks of life, and all sections of society. No matter what type of vegetarian you are, when you see the vegetarian logo you can be assured that product has been made free of any animal materials.

All Natural
The use of non-natural ingredients in Natural Products? It’s true. Some supplement companies still insist on using a variety of unnatural additives to mask natural odors, “punch-up” the flavor; or even replace a naturally sourced therapeutic ingredient for something that was synthesized in a lab.

Use of unnatural additives have been linked to allergic reactions, obesity and type II diabetes, neurological disorders and even cancer. But even if the reaction wasn’t life threatening, how much sense does it make to incorporate their use in “healthful” products? ex: To cover-up the “fishy” taste, a popular fish oil company uses an artificial strawberry flavor. In a DHA product geared toward children and the management of ADD /ADHA, they use an ingredient known to promote neurological problems.

At Nutritional Frontiers we have taken the steps necessary in developing our products to exclude the use of these additives known to cause problems.

**Vegetable Capsule**

Gelatin vs. Vegetarian Capsules
Gelatin is a denatured collagen protein that is derived from the connective tissues (skin, bones, cartilage, hoofs etc.), of vertebrate animals such as pigs and cows.

The result is a brittle, colorless, tasteless, and odorless material. It dissolves easily in hot water and congeals in cold water. It is used as an inexpensive material for supplement capsules, as it retains its form until it dissolves in the stomach.

Vegetarian capsules are made from hydroxypropyl methyl cellulose, consisting of purified water and plant fiber, or cellulose, and meet all the requirements of current FCC (Food Chemical Codex) and USP standards. They are ideal suited for vegetarians and customers have said they are easier to digest than gelatin capsules.

Vegetarian Capsules are:
100% plant based fiber and purified water.
100% non toxic.
100% animal product free
Is certified Halal
Is certified Kosher
Is certified Vegetarian

 **Chewable, Liquids and Powders**

In response to a growing demand by those tired of struggling to take large tablets, Nutritional Frontiers has met the call by introducing a large variety of chewable, liquids and powders. For children and adults of all ages, having these alternatives provide easy to use, convenient dosing, and in many cases, a more flavorful option for your supplement needs.

  

**cGMP**

The manufacturing facilities at Nutritional Frontiers are **cGMP(current Good Manufacturing Practices)** and inspected by the US FDA .
All the Nutritional Frontiers' products are produced in a cGMP facility and come with a 100% guarantee for purity and potency.

Essentially, GMP makes supplement manufacturers responsible for adhering to a specific set of manufacturing processes, safety procedures, and packaging standards to ensure that dietary supplement labels are truthful and that actual dietary supplement contents match the contents on the Supplement Facts label and are not misleading – in any way.

The GMP regulations are set in place to guarantee to consumers that strength and potency claims and ingredients statements on Supplement Facts label panels are accurate. GMP also makes dietary supplement manufacturers responsible for reporting product quality problems.

GMP is meant to reassure consumers that dietary supplements will not have unsafely high ingredients concentrations, will not have harmful contamination from substances such as toxins, bacteria, pesticides, glass, lead, or other heavy materials, and will not have inaccurate ingredients statements on the Supplement Facts label or misleading claims about ingredients and health benefits.

When the FDA issued its final rule about GMP for dietary supplements in June of 2007, Commissioner of Food and Drugs Andrew C. von Eschenbach, stated, *“This rule helps to ensure the quality of dietary supplements so that consumers can be confident that the products they purchase contain what is on the label.”*

**CGMP Final Rule:**

The U.S. Food and Drug Administration issued the final rule establishing regulations to require current good manufacturing practices (cGMPs) for dietary supplements.

The current good manufacturing practices (cGMPs) final rule will require that proper controls are in place for dietary supplements so that they are processed in a consistent manner, and meet quality standards.

The cGMPs apply to all domestic and foreign companies that manufacture, package, label or hold dietary supplements, including those involved with the activities of testing, quality control, packaging and labeling, and distributing them in the U.S.

The rule establishes cGMPs for industry-wide use that are necessary to require that dietary supplements are manufactured consistently as to identity, purity, strength, and composition.

**The requirements include provisions related to:**

The design and construction of physical plants that facilitate maintenance, cleaning, proper manufacturing operations, quality control procedures, testing final product or incoming and inprocess materials, handling consumer complaints, and maintaining records.

To limit any disruption for dietary supplements produced by small businesses, the rule has a staggered three-year phase-in for small businesses. The final cGMPs is effective in June 2008 for large companies. Companies with less than 500 employees have until June 2009 and companies with fewer than 20 employees have until June 2010 to comply with the regulations.

**Interim Final Rule:**

The interim final rule (IFR) establishes a petition process for a manufacturer to apply for exemption from the 100 percent identity testing requirements for dietary ingredients used in manufacturing dietary supplements.

If a manufacturer is granted an exemption, the manufacturer would still be responsible for ensuring the quality of the final dietary supplement product.

The manufacturer would have to provide data in its petition demonstrating that less than 100% identity testing does not materially diminish assurance that the dietary ingredient is the correct dietary ingredient.

The IFR is effective in June 2008 when the cGMP final rule becomes effective. However, there is a 90-day comment period. Based on the comments received, the IFR may be revised.

**Consumer Benefits:**

Consumers should have access to dietary supplements that meet quality standards and that are free from contamination and are accurately labeled.

The rule will give consumers greater confidence that the dietary supplement they use has been manufactured to ensure its identity, purity, strength, and composition.

The rule addresses the quality of manufacturing processes for dietary supplements and the accurate listing of supplement ingredients. It does not limit consumers' access to dietary supplements, or address the safety of their ingredients, or their effects on health when proper manufacturing techniques are used.

**Manufacturers:**

Under the Dietary Supplement Health and Education Act (DSHEA), manufacturers have an essential responsibility to substantiate the safety of their products and for determining that any representations or claims made about their products are substantiated by adequate evidence to show that they are not false or misleading.

The cGMPs will help to ensure manufacturers produce unadulterated and properly labeled dietary supplements.

**Under the cGMP rule, manufacturers are required to:**

* Employ qualified employees and supervisors;
* Design and construct their physical plant in a manner to protect dietary ingredients and dietary supplements from becoming adulterated during manufacturing, packaging, labeling and holding;
* Use equipment and utensils that are of appropriate design, construction, and workmanship for the intended use;
* Establish and use master manufacturing and batch production records;
* Establish procedures for quality control operations;
* Hold and distribute dietary supplements and materials used to manufacture dietary supplements under appropriate conditions of temperature, humidity, light, and sanitation so that the quality of the dietary supplement is not affected;
* Keep a written record of each product complaint related to CGMPs; and
* Retain records for 1 year past the shelf life date, if shelf life dating is used, or 2 years beyond the date of distribution of the last batch of dietary supplements associated with those records.

**Examples of product quality problems that the rule will help prevent are:**

* Dietary supplements that contain ingredients in amounts that are greater than those listed on the label
* Dietary supplements that contain ingredients in amounts that are less than those listed on the label
* Wrong ingredient,
* Other contaminant (e.g., bacteria, pesticide, glass, lead),
* Foreign material in a dietary supplement container,
* Improper packaging, and mislabeled

The interim final rule allows manufacturers to petition FDA for an exemption from the requirement of 100 percent identity testing of one or more dietary ingredients used in manufacturing the dietary supplement. The manufacturer would provide data to demonstrate that its proposed reduced frequency of identity testing does not materially diminish assurance that the dietary ingredient is the correct dietary ingredient. Each petition will be considered on a case by case basis.

**Generally Recognized as Safe (GRAS)**

**"GRAS**" is an acronym for the phrase **Generally Recognized As Safe**. Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the Act), any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive.

Under sections 201(s) and 409 of the Act, and FDA's implementing regulations in 21 CFR 170.3 and 21 CFR 170.30, the use of food substance may be GRAS either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food.

Under 21 CFR 170.30(b), general recognition of safety through scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive and ordinarily is based upon published studies, which may be corroborated by unpublished studies and other data and information.

Under 21 CFR 170.30(c) and 170.3(f), general recognition of safety through experience based on common use in foods requires a substantial history of consumption for food use by a significant number of consumers.

**What does "GRAS" mean?**

"GRAS" is an acronym for the phrase Generally Recognized As Safe. Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the Act), any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive. For example, substances whose use meets the definition of a pesticide, a dietary ingredient of a dietary supplement, a color additive, a new animal drug, or a substance approved for such use prior to September 6, 1958, are excluded from the definition of food additive. Sections 201(s) and 409 were enacted in 1958 as part of the Food Additives Amendment to the Act. While it is impracticable to list all ingredients whose use is generally recognized as safe, FDA published a partial list of food ingredients whose use is generally recognized as safe to aid the industry's understanding of what did not require approval.

**What are the criteria for GRAS status?**

Under sections 201(s) and 409 of the Act, and FDA's implementing regulations in 21 CFR 170.3 and 21 CFR 170.30, the use of a food substance may be GRAS either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food.

Under 21 CFR 170.30(b), general recognition of safety through scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive and ordinarily is based upon published studies, which may be corroborated by unpublished studies and other data and information.

Under 21 CFR 170.30(c) and 170.3(f), general recognition of safety through experience based on common use in foods requires a substantial history of consumption for food use by a significant number of consumers.

**In what way are the criteria for the use of a substance to be GRAS similar to that for the approved use of a food additive?**

Regardless of whether the use of a substance is a food additive use or is GRAS, there must be evidence that the substance is safe under the conditions of its intended use. FDA has defined "safe" (21 CFR 170.3(i)) as a reasonable certainty in the minds of competent scientists that the substance is not harmful under its intended conditions of use. The specific data and information that demonstrate safety depend on the characteristics of the substance, the estimated dietary intake, and the population that will consume the substance.

**In what way are the criteria for the use of a substance to be GRAS different from that for the approved use of a food additive?**

A GRAS substance is distinguished from a food additive on the basis of the common knowledge about the safety of the substance for its intended use. As FDA discussed in a proposed rule to establish a voluntary notification program for GRAS substances (62 Fed. Reg. 18938; April 17, 1997), the data and information relied on to establish the safety of the use of a GRAS substance must be generally available (e.g., through publication in the scientific literature) and there must be a basis to conclude that there is consensus among qualified experts about the safety of the substance for its intended use. Thus, the difference between use of a food additive and use of a GRAS substance relates to the widespread awareness of the data and information about the substance, i.e., who has access to the data and information and who has reviewed those data and information.

For a food additive, privately held data and information about the use of the substance are sent by the sponsor to FDA and FDA evaluates those data and information to determine whether they establish that the substance is safe under the conditions of its intended use (21 CFR 171.1).

For a GRAS substance, generally available data and information about the use of the substance are known and accepted widely by qualified experts, and there is a basis to conclude that there is consensus among qualified experts that those data and information establish that the substance is safe under the conditions of its intended use. (proposed 170.36 (c)(4)(i)(C))